Supreme Court, U.S.
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No. 06-

IN THE

Supreme Court of the United States

NEUTRINO DEVELOPMENT CORPORATION,

Petitioner,

v.

SONOSITE, INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

When is a patent drawing alone adequate disclosure to support a claim limitation so as to satisfy the written description requirement of 35 U.S.C. § 112?

When is a patent drawing alone adequate disclosure to support later amendments to the specification and claims so as to avoid the "new matter" prohibition of 35 U.S.C. § 132?

PARTIES TO THE PROCEEDING

Petitioner is Neutrino Development Corporation, a Texas corporation.

Respondent is SonoSite, Inc., a Washington corporation.

Counterclaim Defendant, Richard Redano, was not a party to the appeal to the United States Court of Appeals for the Federal Circuit and is not a party to this Petition.

STATEMENT PURSUANT TO RULE 29.6

Petitioner, Neutrino Development Corporation, has no parent corporations and no publicly held company owns more that 10% of its stock.

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I. PETITION FOR A WRIT OF CERTIORARI

Petitioner respectfully petitions for a writ of certiorari to review the judgments of the Court of Appeals for the Federal Circuit and of the United States District Court for the Southern District of Texas.

II. OPINIONS AND ORDERS BELOW

The United States Court of Appeals for the Federal Circuit did not render a written opinion, but instead, on December 8, 2006, it affirmed the judgment of the lower court through a judgment of affirmance pursuant to Rule 36 of the Federal Circuit Rules. This order, which is included within Petitioner's Appendix at 1a, may be found at 2006 WL 3780734. Similarly, the Federal Circuit, in denying the request for a panel rehearing or rehearing en banc, did not issue a written opinion, but delivered an order on January 19, 2007, which is included within Petitioner's Appendix at 114a. The opinion of the United States District Court for the Southern District of Texas, *Neutrino Development Corp. v. SonoSite, Inc.*, 423 F. Supp. 2d 673 (S.D. Tex. 2006) (3a), is published, and it was issued on March 21, 2006.

Other published opinions of the United States District Court for the Southern District of Texas are as follows: *Neutrino Development Corp. v. SonoSite, Inc.*, 410 F. Supp. 2d 529 (S.D. Tex. 2006) (46a); *Neutrino Development Corp. v. SonoSite, Inc.*, 337 F. Supp. 2d 942 (S.D. Tex. 2004) (30a); *Neutrino Development Corp. v. SonoSite, Inc.*, 337 F. Supp. 2d 937 (S.D. Tex. 2004) (18a).

Other judgments and orders from the United States District Court for the Southern District of Texas are as

follows: *Neutrino Development Corp. v. SonoSite, Inc.*, No. H-01-2484, 2007 WL 998636 (S.D. Tex. Mar. 30, 2007) (105a) (awarding costs); *Neutrino Development Corp. v. SonoSite, Inc.*, No. H-01-2484, 2007 WL 1040697 (S.D. Tex. Mar. 30, 2007) (89a) (denying attorneys' fees).

III. JURISDICTION

The United States District Court for the Southern District of Texas entered judgment on March 21, 2006, and the United States Court of Appeals for the Federal Circuit entered judgment on December 8, 2006. The Federal Circuit entered the order denying the request for panel rehearing and rehearing en banc on January 19, 2007. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

IV. STATUTES INVOLVED

35 U.S.C. § 112, ¶ 1, provides as follows:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The full text of § 112 is included within the Appendix at 133a.

35 U.S.C. § 132(a) provides, in pertinent part, that "[n]o amendment shall introduce new matter into the disclosure of the invention." The full text of § 132 is included within the Appendix at 135a.

V. STATEMENT OI THE CASE

This is a patent infringement case, and the United States District Court for the Southern District of Texas, which was the court of first instance, had jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a) because this case arose under the patent laws of the United States (35 U.S.C. § 100).

A. Material Facts

Richard T. Redano, an independent inventor of numerous patents, and a registered patent attorney, is the inventor of United States Patent No. 6,221,021, titled, "Method and Apparatus for Penile Hemodynamic Stimulation, Monitoring, and Drug Delivery Acceleration" ("the '021 patent"). Neutrino Development Corporation ("Neutrino"), a technology marketing and licensing corporation, is the assignee of the '021 patent.

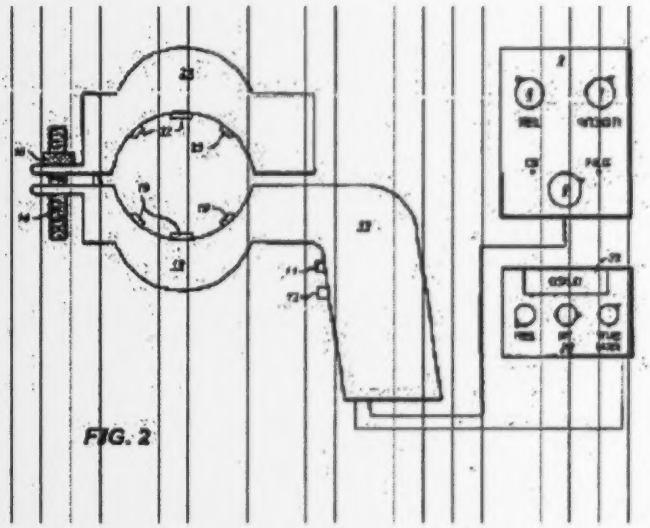
SonoSite, Inc. ("SonoSite"), is a manufacturer and provider of diagnostic medical ultrasound devices and services. Specifically, SonoSite manufactures the following products, all of which have been accused of infringing the '021 patent: (1) SonoSite 180; (2) SonoHeart; (3) SonoSite 180 Plus; and (4) SonoHeart Plus. These products are portable, hand-held devices, capable of measuring certain hemodynamic parameters—such as blood flow—through the use of ultrasound. *Neutrino Dev. Corp.*, 337 F. Supp. 2d at 938.

The '021 patent claims priority from, and is a continuation-in-part of, an application filed on September 9, 1997, which is now United States Patent No. 5,947,901 ("the '901 patent"). The '021 patent discloses apparatus and method embodiments wherein an ultrasound device may be used in a therapeutic mode and/or a diagnostic mode. (U.S. Patent No. 6,221,021 B1, col. 1, lines 15–17.) In a therapeutic mode, the device is used to correct erectile dysfunction by stimulating the flow of blood in a penis (U.S. Patent No. 6,221,021 B1, col. 1, lines 1–22), whereas in a diagnostic mode, the device measures certain hemodynamic parameters, such as blood flow. (U.S. Patent No. 6,221,021 B1, col. 7, lines 25–27.) The claims in the '021 patent are directed only to the diagnostic embodiment of the disclosed apparatus.

On May 10, 2000, an amendment was filed in response to the initial office action. The amendment at issue appears at col. 6, lines ~~18-20~~, and it reads as follows: "As shown in FIG. 2, the ultrasonography generator unit 30 is sized to be grasped or held in a user's hand." (U.S. Patent No. 6,221,021 B1, col. 6, lines 18-20; Amendment and Resp. to First Office Action at 5, lines 25-26; Petitioner's App. at 8a n.1.) In that same amendment, new claims were added, which included element "(a)." Element "(a)" contains the following language: "a portable body sized to be hand held." (Amendment and Resp. to First Office Action at 5-6.) The Examiner entered the amendment and the new claims without objection. (Amendment and Resp. to First Office Action at 5-6.)

Throughout the stages of this case, Neutrino has argued that element "(a)" finds support in Fig. 2, which is the drawing at issue, of the original '021 patent application. The

claim element in question is element "32" in the drawing. The following illustration is Fig. 2, as it appears in the original application:



B. Proceedings Below

On July 24, 2001, Neutrino filed an action for patent infringement against SonoSite, alleging that SonoSite's hand-held diagnostic medical ultrasound devices infringe the '021 patent.

After holding a *Markman* hearing on February 20, 2002, the district court, on August 21, 2003, construed the meaning of certain words and phrases. Only one of the phrases—"a portable body sized to be hand held"—is relevant to this petition. That phrase appears in each of the independent claims at issue in the '021 patent as element "(a)." The district court construed the phrase as follows: "'A portable body sized to be hand held'—A body that is sized such that it can be

held by hand and, so held, moved from one location to another." (132a.)

On March 21, 2006, the district court granted SonoSite's motion for summary judgment of patent invalidity, holding that claims 8, 20, and 25, and all claims dependent thereon, of the '021 patent were invalid for failure to comply with 35 U.S.C. §§ 112, ¶ 1, and 132(a). (3a.) On the same day, the district court entered its Final Judgment, in which it did the following: (1) invalidated claims 8, 20, and 25, and all claims depending thereon; (2) reversed its summary judgment finding of literal infringement of these claims; and (3) dismissed with prejudice Neutrino's claims of infringement. *Neutrino Dev. Corp.*, 423 F. Supp. 2d at 680. The district court found claims 8, 20, and 25, and all claims depending thereon, invalid because of "new matter" that it determined was found in element "(a)" of each claim ("a portable body sized to be hand held").

Neutrino appealed to the United States Court of Appeals for the Federal Circuit. In the briefs that it filed in the Federal Circuit, Neutrino argued, *inter alia*, that the district court erred in holding that the claims were invalid because the district court disregarded binding precedent that provides that patent drawings *alone* may be relied upon, in certain situations, to support claim limitations. After oral argument, the Federal Circuit affirmed the judgment of the district court without rendering a written opinion. Neutrino petitioned the Federal Circuit for a rehearing and for a rehearing en banc, but the Federal Circuit denied the petition.

VI. REASONS FOR GRANTING THE PETITION

This Court should grant Neutrino's Petition for a Writ of Certiorari for the following reasons: (1) the law in the Federal Circuit relating to the reliance upon patent drawings *alone* is in conflict, and in need of clarification; and (2) this Court has never addressed whether, and to what extent, patent drawings *alone* may be relied upon to support claim limitations, and such an important question should be settled by this Court. *See* Sup. Ct. R. 10 (providing reasons considered by the Court when determining whether to grant a petition for a writ of certiorari).

A. Binding Federal Circuit Law Is in Conflict with Other Binding Federal Circuit Law

Ordinarily, conflicts in the law regarding the same matter occur between different courts located in different jurisdictions, and on numerous occasions, this Court has granted writs of certiorari to resolve such conflicts when the conflicts concerned the same important matters. *See* Thomas W. Adams, *The 1988 Revision of 28 U.S.C. § 1391(c): Corporate Venue Is Now Equivalent to In Personam Jurisdiction Effects on Civil Actions for Patent Infringement*, 39 Clev. St. L. Rev. 357, 369 (1991) ("Historically, many of the Supreme Court's grants of certiorari have been necessitated by conflicts between the Circuit Courts of Appeal."). It is rather unusual for there to exist an actual conflict in the law of the same circuit, and this is because conflicting decisions are overruled by the same circuit that rendered them, thereby removing the conflict. *See Wisniewski v. United States*, 353 U.S. 901, 902 (1957) (stating that "[i]t is primarily the task of a Court of Appeals to reconcile

its internal difficulties"). Thus, there is normally little need for this Court to become involved.

However, since the advent of the United States Court of Appeals for the Federal Circuit, the Federal Circuit is the only appellate court, other than this Court, that can hear patent-related appeals, where the patent issue is raised in the complaint, as in the case at bar. *See* 28 U.S.C. § 1295(a)(1) (2006) (providing that "[t]he United States Court of Appeals for the Federal Circuit shall have exclusive jurisdiction . . . of an appeal from a final decision of a district court of the United States . . . if the jurisdiction of that court was based, in whole or in part, on [28 U.S.C. § 1338]"). Consequently, if one Federal Circuit decision conflicts with another Federal Circuit decision concerning the same matter, and both decisions still stand, such a conflict will rarely be addressed because it is assumed that the Federal Circuit will resolve conflicts within its own court. *See Wisniewski*, 353 U.S. at 902. Moreover, it is simply counterintuitive to think that the same court could be in conflict with itself. Nevertheless, with regard to the issue presented in this petition, the Federal Circuit has created a conflict between two prior decisions, both of which still stand.

1. *The Conflict at Issue*

The conflict at issue relates to whether, and to what extent, patent drawings alone may be relied upon to support claim limitations. The Federal Circuit has decided two seminal cases related to this matter[1]: (1) *Hockerson-*

[1] There are other Federal Circuit cases that have addressed this issue as well. *See, e.g., Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1566-67 (Fed. Cir. 1991) ("[T]he possibility that the '081 drawings may provide an adequate § 112 'written description' of the subject matter of . . . the claims . . . should have been considered.").

Halberstadt, Inc. v. Avia Group International, Inc., 222 F.3d 951 (Fed. Cir. 2000); and (2) *Koito Manufacturing Co. v. Turn-Key-Tech, LLC*, 381 F.3d 1142 (Fed. Cir. 2004). Both decisions still stand, with one, Hockerson-Halberstadt, holding that support for *precise* proportions made in claims cannot be found in drawings, and the other, *Koito*, determining that drawings can support claim limitations when those limitations disclose *relative* dimensions.

Until recently, these two decisions were not in conflict. However, after the district court issued its opinion in which it announced that situations regarding "precise" proportions recited in the claims were the same, under Federal Circuit law, as situations regarding "relative size,"[2] it created a conflict between its decision and those of the Federal Circuit, and the Federal Circuit was presented with an opportunity to correct this misinterpretation of its own decisions. Yet the Federal Circuit did not to do so, despite Neutrino having apprised it of the inconsistency on two separate occasions.[3] Instead of addressing, and resolving, this important issue, the Federal Circuit affirmed the district court's judgment without even rendering a written opinion, thus creating the conflict at issue. Accordingly, what was once lucid Federal Circuit law is now conflicted. As such, a patentee confronted

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[2] *Neutrino Dev. Corp.*, 423 F. Supp. 2d at 678 (stating that "the Court does not believe that the Federal Circuit in *Hockerson-Halberstadt* intended for 'precise proportions' to carry a meaning distinct from 'relative size'").

[3] In its Brief and in its Petition for Rehearing and Suggestion for Rehearing En Banc, Neutrino notified the Federal Circuit that the district court had misconstrued binding Federal Circuit law. (Br. of Pl.-Appellant at 20-21; Pet. for Reh'g & Suggestion for Reh'g En Banc at 1-9.)

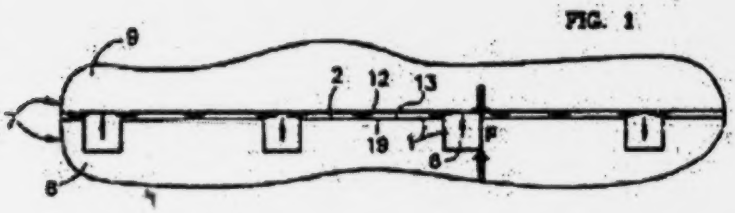
with the issue at hand is faced with the precarious and unenviable task of attempting to determine whether the panel of judges deciding the case will follow one decision or the other. This creates uncertainty in the law, which directly affects all patent holders and potential patent holders, and, on a grander scale, American business as a whole, for if such a conflict is not resolved, a myriad of patents could be invalidated.

2. *Neutrino's Reliance upon Koito*

Neutrino relied upon *Koito,* and it was never determined by either the district court or the Federal Circuit that the '021 patent did not fit within the reasoning of that decision. Rather, the district court misconstrued Federal Circuit precedent, and the Federal Circuit exacerbated this problem by affirming the judgment, thereby unnecessarily creating a conflict.

Neutrino's reliance upon Koito was founded upon the fact that the Federal Circuit in that case decided that drawings *alone* could be relied upon to support claim limitations, *when those limitations relate to* ***relative*** *dimensions. Koito Mfg. Co.,* 381 F.3d at 1155. In the present case, Figure 1 of the '268 patent clearly shows that flow channel 6 is 'significantly thicker and wider' than the adjacent mold cavity 2. Figure 1 thus demonstrates that the inventor was 'in possession' of the patent claims, including the claim limitation speaking to the relative dimensions of the flow channel, and thus that

the written description requirement was satisfied." (emphasis added)). The drawing that follows is Figure 1 from *Koito*:



The claim limitation at issue in this case—"a portable body sized to be hand held"—is nothing more than a limitation relating to relative size.[4] It does not speak to any precise proportions, and because of this, *Hockerson-Halberstadt,* and its prohibition against reliance upon drawings to support precise proportions, is inapplicable.

3. *The Only Solution Is a Granting of the Writ*

Rarely does this Court hear cases involving only an intracircuit conflict created by different panels of judges deciding the same matter in different, and conflicting, ways. In denying petitions based on intracircuit conflicts, this Court

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[4] This is obvious because no specific measurements, relating to the portable body, were provided, which precludes reaching a determination that any precise proportions are involved. Moreover, the portable body, as it is described in the limitation, must relate to something. That something is the hand of a human such as a hand grasping a pistol grip 10 in Fig. 2. Furthermore, there exists an abundance of evidence, offered by Neutrino's experts, supporting the fact that the disclosure in the drawing (Fig. 2) reasonably conveys to one skilled in the art that the claim limitation at issue finds support in the drawing.

has explained that such conflicts should be resolved by the court of appeals in which the conflict arose. *See Wisniewski*, 353 U.S. at 902. This is accomplished through en banc review. *See* Fed. R. App. P. 35(a)(1) (explaining that "[a]n en banc hearing or rehearing is not favored and ordinarily will not be ordered unless . . . en banc consideration is necessary to secure or maintain uniformity of the court's decisions"). As discussed in Part VI.B., below, there is another reason for granting the writ aside from the intracircuit conflict issue. Nevertheless, even if the intracircuit conflict was the only argued basis for granting the writ, the Court should still grant it because the reasoning behind the Court's denial of petitions for writ based upon intracircuit conflicts is inapposite to the present scenario. This is because the foundation upon which that reasoning has been based is, in the instant case, on less than solid ground due to the Federal Circuit's denial of Neutrino's Petition for Rehearing and Suggestion for Rehearing En Banc.

It is also worth mentioning that this Court granted certiorari to hear the case of *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995), despite the fact that that case had already been decided by the Federal Circuit while sitting en banc. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996). Prior to the Federal Circuit's en banc decision, there was an apparent conflict between different Federal Circuit decisions relating to the same matter (claim construction). *See Markman*, 52 F.3d at 976 ("The opinions of this court have contained some inconsistent statements as to whether and to what extent claim construction is a legal or factual issue, or a mixed issue."). Although this conflict was resolved through the en banc rehearing of the case, this Court still granted certiorari. This is further support for the argument that the Court should grant

certiorari in the instant action because the conflict at issue was not resolved by the Federal Circuit.

Neutrino diligently pursued every option available to it in attempting to convince the Federal Circuit that a conflict existed between binding Federal Circuit precedent, and this diligence is evidenced by the arguments presented by Neutrino in its petition for rehearing. Yet the Federal Circuit refused to address the conflict, thereby failing to adhere to the doctrine of stare decisis. To put it another way, the system failed, and it is desperately in need of repair by this Court because the conflict will not be resolved by the Federal Circuit.

Therefore, the newly created conflict regarding whether patent drawings may be relied upon to support claim limitations should be resolved by this Court, especially after considering that the Federal Circuit was presented with an opportunity to resolve it, but refused to do so.

B. This Court Should Settle the Issue of Whether, and to What Extent, Patent Drawings May Be Relied Upon

The United States Supreme Court has never directly addressed the issue presented, and it is imperative that the Court now resolve whether, and in what instances, patent drawings *alone* may be relied upon to support claim limitations. This issue directly affects two of the most fundamental federal statutes relating to the law of patents: (1) 35 U.S.C. § 112; and (2) 35 U.S.C. § 132. One of these statutes, § 112, requires a written description of the invention to be patented, and without such a written description, no patent will issue. The other, § 132, prohibits new matter from

being added by amendment into the disclosure of the invention. If either of these statutes are ignored or construed too liberally—either by a patentee, the United States Patent and Trademark Office, or a court—then an overabundance of patents will issue, many of which will likely be declared invalid, with the end result being a complete waste of judicial resources. On the opposite end of the spectrum, if the statutes are applied in an aggressively rigid fashion, there will be a dearth of patents because many inventions deserving of a patent will go unpatented, and many deservingly valid patents will be invalidated.

As the issue now stands, based upon the Federal Circuit's affirmance of the district court's published opinion, a patentee is likely[5] precluded—regardless of the circumstances—from ever relying upon drawings *alone* to find support for claim limitations. This places patent law in the latter situation described above. Such a result is inimical to the patent system, not to mention that it practically renders meaningless a federal statute—35 U.S.C. § 113, which requires drawings. *See* 35 U.S.C. § 113 (2001)

> The applicant shall furnish a drawing where necessary for the *understanding* of the subject matter sought to be patented. . . . Drawings submitted after the filing date of the application may not be used (i) to overcome any insufficiency of the specification due to lack of an enabling disclosure or otherwise inadequate disclosure therein, or (ii) to supplement the original

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[5] The word "likely" is employed because the law relating to this issue is altogether ambiguous due to the conflict discussed in Part VI.A. of this petition.

> disclosure thereof for the purpose of interpretation of the scope of any claim.

(Emphasis added).

Whether a patentee may rely upon patent drawings to support claim limitations affects the very corpus of patent law, and such an important issue should be decided by this Court to bring clarity and consistency to the law. For as it currently exists, it is entirely unclear whether a patentee may rely upon patent drawings to support claim limitations.

VII. CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX

APPENDIX A — JUDGMENT OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DATED AND FILED DECEMBER 8, 2006

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 2006-1316

NEUTRINO DEVELOPMENT CORPORATION,

Plaintiff/Counterclaim Defendant-Appellant,

and

RICHARD T. REDANO,

Counterclaim Defendant,

v.

SONOSITE, INC.,

Defendant/Counterclaimant-Appellee.

JUDGMENT

ON APPEAL from the UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF TEXAS

In CASE NO(S). 01-CV-2484

This CAUSE having been heard and considered, it is

ORDERED and ADJUDGED:

Appendix A

Per Curiam: (MAYER and PROST, *Circuit Judges*, WHYTE, *District Judge**):

AFFIRMED. See Fed. Cir. R. 36.

ENTERED BY ORDER OF THE COURT

s/ Jan Horbaly
Jan Horbaly, Clerk

DATED DEC -8 2006

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* Honorable Ronald M. Whyte, United States District Court for the Northern District of California, sitting by designation.

APPENDIX B — MEMORANDUM AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF TEXAS, HOUSTON DIVISION DATED MARCH 21, 2006

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

CIVIL ACTION NO. H-01-2484

NEUTRINO DEVELOPMENT CORPORATION,

Plaintiff,

v.

SONOSITE, INC.,

Defendant.

MEMORANDUM AND ORDER

Pending before the Court is Defendant's Motion for Summary Judgment of Invalidity Based on New Matter (Dkt.# 279). The Court, after reviewing the motion, the responses of the parties and the relevant law, is of the opinion that the motion should be GRANTED.

Factual and Procedural Background

This is an action for patent infringement brought by Neutrino Development Corporation ("Neutrino") against Sonosite, Inc. ("Sonosite"). Neutrino is the owner of United

States Patent No. 6,221,021 ("the '021 patent"). Neutrino alleges that four devices manufactured and marketed by Sonosite, the Sonosite 180, SonoHeart, Sonosite 180 PLUS, and the SonoHeart PLUS, infringe on the '021 patent.

The '021 patent application was filed on May 30, 1999, and claimed priority to an earlier patent application, Application Serial No. 08/926, 209, filed on September 9, 1997, which was issued as U.S. Patent No. 5,947,901 ("the '901 patent application" and the " '901 patent," respectively). The '021 patent application, entitled "Method and Apparatus for Penile Hemodynamic Stimulation, Monitoring, and Drug Delivery Acceleration," described a device for "stimulating and/or monitoring hemodynamic activity, such as blood flow, in a penis." *U.S. Patent No. 6,221,021* at col. 1, ll. 15-16. On February 4, 2000, the U.S. Patent & Trade Office ("PTO") rejected all of the claims in the original '021 Patent Application. In May 2000, Redano amended the pending '021 patent application. Part of that amendment became the claims of the '021 patent, which was issued on April 24, 2001.

Defendant Sonosite began as a division of ATL Ultrasound, Inc., and was spun off as a public company in April 1998. Sonosite unveiled its first public product in the realm of hand-carried ultrasound devices, the Sonosite 180, on May 17, 1999. Sonosite began selling the device in June 1999. In January 2000, Sonosite launched its second product, the SonoHeart. In April 2001, Sonosite launched a new generation of these two devices with its introduction of the SonoSite 180 PLUS and the SonoHeart PLUS.

Appendix B

On July 24, 2001, Neutrino filed this action, alleging that Sonosite had illegally used Redano's invention and infringed the '021 patent. Sonosite answered the complaint on August 14, 2001, asserting that the '021 patent claims are not infringed and are invalid, and counterclaimed for declaratory judgment of non-infringement and invalidity.

On February 20, 2002, after extensive briefing, the Court held a one-day *Markman* hearing on claim construction. On October 9, 2002, the Court stayed all proceedings pending the Court's *Markman* and summary judgment rulings. The Court issued its claim construction on August 21, 2003. Subsequently, the Court granted Neutrino's Motion for Summary Judgment on Infringement (Dkt. # 136) finding that Sonosite's devices literally infringed the '021 patent and that the reverse doctrine of equivalents was not applicable (Dkt.# 162).

Summary Judgment Standard

Summary judgment is proper if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); *see also Christopher Village, LP v. Retsinas*, 190 F.3d 310, 314 (5th Cir.1999). "For any matter on which the non-movant would bear the burden of proof at trial . . . , the movant may merely point to the absence of evidence and thereby shift to the non-movant the burden of demonstrating by competent summary judgment proof that there is an issue of material fact warranting trial." *Transamerica Ins. Co. v.*

Avenell, 66 F.3d 715, 718-19 (5th Cir.1995); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 323-25, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). To prevent summary judgment, the non-movant must "respond by setting forth specific facts" that indicate a genuine issue of material fact. *Rushing v. Kansas City S. Ry. Co.*, 185 F.3d 496, 505 (5th Cir.1999).

When considering a motion for summary judgment, the Court must view the evidence in the light most favorable to the non-movant and draw all reasonable inferences in favor of the non-movant. *See Samuel v. Holmes*, 138 F.3d 173, 176 (5th Cir.1998); *Texas v. Thompson*, 70 F.3d 390, 392 (5th Cir.1995). "The court may not undertake to evaluate the credibility of the witnesses, weigh the evidence, or resolve factual disputes; so long as the evidence in the record is such that a reasonable jury drawing all inferences in favor of the nonmoving party could arrive at a verdict in that party's favor, the court must deny the motion." *Int'l Shortstop, Inc. v. Rally's, Inc.*, 939 F.2d 1257, 1263 (5th Cir.1991). However, the non-movant cannot avoid summary judgment by presenting only "conclusory allegations," or "unsubstantiated assertions," such as the bare allegations of a complaint, but must present sufficient evidence, such as sworn testimony in a deposition or affidavit, to create a genuine issue of material fact as to the claim asserted. *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 (5th Cir.1994) (en banc).

Patent cases are as amenable to summary judgment as any other case when no genuine issue of material fact exists and the movant is entitled to judgment as a matter of law. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997); *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1576-77 (Fed.Cir.1989); *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1116 (Fed.Cir.1985).

However, a court should apply a somewhat more exacting scrutiny to a motion for summary judgment based on invalidity because there is a statutory presumption that an issued patent is valid. This presumption "is based in part on the expertise of patent examiners presumed to have done their jobs." *Brooktree Corp. v. Adv. Micro Devices, Inc.*, 977 F.2d 1555, 1574 (Fed.Cir.1992). The Federal Circuit has held that " 'the fact that the Patent Office allows . . . an amendment without objection thereto as new matter (within the meaning of Title 35 U.S.C. § 132) is entitled to an especially weighty presumption of correctness.' " *Id.* (quoting *In re Smythe*, 480 F.2d 1376, 1385 n. 5 (Cust. & Pat.App.1973)). The Court has taken this strong presumption into due consideration.

Analysis

The new matter prohibition of 35 U.S.C. § 132 "serves to ensure that the patent applicant was in full possession of the claimed subject matter on the application filing date." *TurboCare Division of Demag Delaval Turbomachinery Corp. v. General Elec. Co.*, 264 F.3d 1111, 1118 (Fed.Cir. 2001). The relevant portion of § 132(a) reads, "[n]o amendment shall introduce new matter into the disclosure of the invention." When an applicant amends the specification and/or claims after the original filing date, as Richard Redano did in this case, "the new claims or other added material must find support in the original specification." *Id.* (citing *Schering Corp. v. Amgen Inc.*, 222 F.3d 1347, 1352 (Fed.Cir.2000)). The relevant inquiry is whether one of ordinary skill in the art would have determined from the original application that the applicant was in possession of the amended subject matter at the time of the original application filing date. *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575 (Fed.Cir.1985). In simpler terms, an amendment

may only clarify, not change, the written description in the original patent application.

Sonosite contends that the claims of the '021 patent that are the subject of this lawsuit [1] are invalid because the hand-held size of the ultrasonography generator was "new matter" under § 132 introduced through amendments to the specifications and claims of the '021 patent application. Sonosite contends that the amendments specifying that the ultrasonography generator is sized to be hand-held found support neither explicitly nor inherently in the original patent application. Neutrino argues in response that (1) the diagrams in the original patent application indicate by proportion that the ultrasonography generator would be sized small enough to be hand-held, and (2) a genuine issue of material fact exists as to whether a person of ordinary skill in the art would have readily understood U.S. Pat. No. 5,578,060 ("Pohl patent"), incorporated by reference into the '021 patent application, to describe a hand-held ultrasonography generator. The Court will consider each of these arguments below.

Neutrino contends that the hand-held size of the ultrasonography generator was disclosed *inherently* in the original application. The Federal Circuit has held that "[i]n order for a disclosure to be inherent, 'the missing descriptive matter must necessarily be present in the [original] application's specification such that one skilled in the art would recognize such a disclosure." *TurboCare*, 264 F.3d at 1119 (quoting *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1159 (Fed.Cir.1998)). Neutrino

1. Neutrino has asserted that Sonosite is infringing claims 8-14 and 20-27. See Dkt. # 75, p. 4. Of those, claims 8, 11-13, 20, 21, 23-27 include (directly or by reference) the amended language indicating that the ultrasonography generator is sized to be hand-held.

argues that the proportions implied by the diagrams in the original application and in the Pohl patent necessarily lead one of ordinary skill in the art to conclude that the ultrasonography generator was intended to be small enough to be hand-held. In response, Sonosite argues that the possibility that the ultrasonography generator depicted in the diagrams and disclosed in the Pohl patent *could* be sized to be hand-held is not sufficient to qualify as inherent disclosure. Based on the analysis adopted by the Federal Circuit, the Court agrees with Sonosite that one of ordinary skill in the art must conclude that the diagrams and/or the Pohl patent *necessarily* disclose a hand-held ultrasonography generator. *TurboCare*, 264 F.3d at 1119. The conclusion that the diagrams or Pohl patent *might* disclose a hand-held ultrasonography generator is insufficient to stand as inherent support for an application amendment. To survive this motion for summary judgment, the diagrams must unequivocally depict an ultrasonography generator sized to be hand-held and/or the Pohl patent must explicitly disclose an ultrasonography generator that is sized to be hand-held. In the following paragraphs, the Court will review the specification diagrams and the Pohl patent to determine whether any reasonable jury could determine that a person of ordinary skill in the art of designing, testing, and building medical ultrasound devices could conclude that the diagrams and/or patent incorporated by reference necessarily disclose a hand-held ultrasonography generator.

1. Patent Application Diagrams

Sonosite argues that the drawings in the original '021 patent application do not disclose the size of the ultrasonography generator because (1) patent drawings cannot be relied upon to show particular sizes where the specification

is silent on the issue of size, and (2) the proportions loosely depicted in the drawings, if taken literally, would produce an untenable result. Neutrino objects to the applicability of the cases cited by Sonosite for the proposition that drawings cannot establish sizes on the grounds that these cases do not preclude reliance on drawings to show general proportions as opposed to specific dimensions. Neutrino contends that the original specification explicitly discloses a hand-held transducer housing (a fact that Sonosite does not dispute) and the drawings show the proportionate size of each component of the claimed invention in relation to the transducer housing. In Figure 2, reproduced below, the ultrasound generator and the ultrasonography generator are smaller than the hand-held transducer housing.[2]

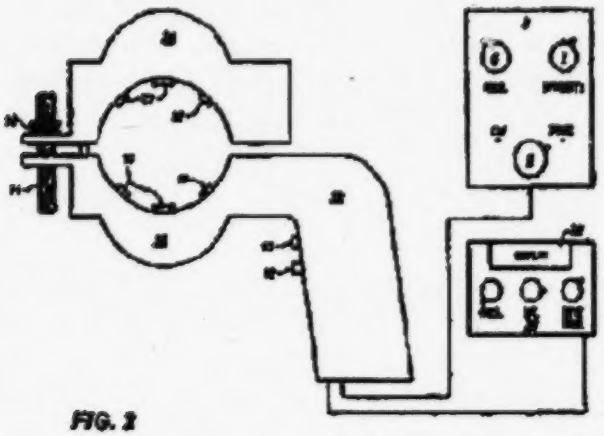

FIG. 2

2. Unit 32 of Figure 2 depicts the ultrasonography generator. The component comprised of units 10, 18, and 24 represents the hand-held transducer housing.

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Neutrino contends that one of ordinary skill in the art would understand from this drawing that the ultrasonography generator is proportionately smaller than the hand-held transducer housing and, therefore, is itself sized to be hand-held. However, Figure 2 contains neither a scale nor dimensions and under well-established Federal Circuit precedent, "patent drawings do not define the precise proportions of the elements and may not be relied upon to show particular sizes if the specification is completely silent on the issue." *Hockerson-Halberstadt, Inc. v. Avia Grp. Int'l*, 222 F.3d 951, 956 (Fed.Cir.2000). Neutrino argues that *Hockerson-Halberstadt* and other similar cases do not apply to depictions of general proportions and "relative size."[3] Neutrino also argues that the '021 patent application specification was not "completely silent" on the issue of relative size because it incorporated the Pohl patent by reference. The Court rejects the latter argument on the grounds that the requirement that the specification not be "completely silent" on the issue of size in order to imply size in a drawing necessitates an explicit disclosure in the specification, not an implicit disclosure such as another patent incorporated by reference. To that end, the Pohl patent also lacks any explicit reference to the size of the ultrasonography generator. The implication of size within another patent incorporated by reference is insufficient to support contentions about the relative size of components depicted in an unspecific drawing. No reasonable jury could determine that a person of ordinary skill in the art would have readily recognized the size (specific or relative) of the ultrasonography generator from the drawings in the '021 patent.

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3. Dkt. # 292, p. 9.

Furthermore, the Court does not believe that the Federal Circuit in *Hockerson-Halberstadt* intended for "precise proportions" to carry a meaning distinct from "relative size." The issue on appeal in *Hockerson-Halberstadt* was "whether the district court correctly construed the term 'central longitudinal groove to require that the width of the groove' must be less than the combined width of the fins." *Hockerson-Halberstadt*, 222 F.3d at 954. The defendant in *Hockerson-Halberstadt* made the argument that statements submitted by the inventor during the prosecution about the width of the groove conflicted with the drawings in the specification of the original patent application and, therefore, the conflicting prosecution history should not be used to construe the claims. The Federal Circuit rejected the defendant's argument on the grounds that the patent "is devoid of any indication that the *proportions* of the groove and fins are drawn to scale." *Id.* at 956 (emphasis added). The Federal Circuit determined that the drawings could not be relied upon to establish the size of the groove *relative to* the fins. Ultimately, the Federal Circuit held that "a reasonable competitor, being aware that figures in a patent are not drawn to scale unless otherwise indicated, would" have accepted the specific statements about size in the prosecution history.[4]

4. The Court notes that *Hockerson-Halberstadt* was about claim construction, not the issue of "new matter." As in the present case, the district court in *Hockerson-Halberstadt* would not have evaluated the propriety of the amended language under § 132 while issuing the claim construction. The process of claim construction assumes the validity of the issued patent. The defendant in *Hockerson-Halberstadt* made the argument that a particular claim should be interpreted in light of the apparent proportions in the specification drawings. Because specific language in the prosecution history

(Cont'd)

The Court finds that it was precisely the sort of argument that Neutrino attempts to advance here that the Federal Circuit sought to preclude in *Hockerson-Halberstadt.* Put simply, the Federal Circuit prohibits reliance upon unspecific drawings to support claim limitations.[5] Therefore, the Court finds that no reasonable juror could conclude that a person of ordinary skill in the art would have relied upon the relative sizes depicted in the specification drawings of the original '021 patent application to determine the size of the ultrasonography generator.

2. The Pohl Patent

Sonosite contends that the Pohl patent does not disclose an ultrasonography generator sized to be hand-held on the grounds that (1) the Pohl patent does not disclose an ultrasonography generator at all, and (2) even if unit 14 depicted in Figure 1 of the Pohl patent can be treated as an

(Cont'd)

explained the relative size of the groove, the court's analysis pitted the prosecution disclaimer against the drawings. However, had there been no statements about relative size in the prosecution history, the plaintiff still would not have been able to rely on the specification drawings to establish relative size. The outcome in this alternative scenario would have been a claim construction without any specification about size.

5. Because the drawings in the original patent application cannot support the amendment pertaining to the hand-held size of the ultrasonography generator, it is not necessary to explore whether the proportions offered by Neutrino are so factually untenable as to warrant summary judgment. The Court does, however, note that the relative sizes depicted in Figure 2, if taken literally, would suggest an ultrasonography generator not merely hand-held, but small enough to fit in the palm of one's hand.

equivalent of the ultrasonography generator in the '021 patent, the device disclosed in the Pohl patent is not *necessarily* sized to be hand-held. The Court will address the latter argument first because it is dispositive.

The component identified in the Pohl patent as analogous to the ultrasonography generator in the '021 patent is depicted as unit 14 in Figure 1 of the Pohl patent. The Pohl patent states that Figure 1 depicts "a relatively large physical therapy apparatus."[6] However, the description also states that the preferred embodiment depicted in Figure 1 could "be much smaller so as to be portable without departing from the spirit and scope of the present invention."[7] If a device sized small enough to be portable falls within the scope of the Pohl patent, it follows that unit 14, which is a component of the device, can potentially be sized small enough to be portable without broadening the scope of the patent. As an initial matter, Sonosite argues that being sized to be "portable" is not equivalent to being sized to be hand-held. Sonosite contends that portable could mean "capable of being moved from place to place" on a cart.[8] However, even if the Court accepts that a person of ordinary skill in the art would understand that unit 14 is equivalent to the ultrasonography generator in the '021 patent and that "portable" can include a size small enough to be hand-held, the Pohl patent still fails to disclose a hand-held ultrasonography generator sufficient to inherently support that limitation as an amendment to the original '021 patent application. The Federal Circuit has specified that

6. Dkt. # 279, Exhibit 11 (Pohl patent).

7. *Id.*

8. Dkt. # 279, p. 12.

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"[t]he missing descriptive matter *must necessarily be present* in the [original] application's specification such that one skilled in the art would recognize such a disclosure." *TurboCare*, 264 F.3d at 1119 (emphasis added). The possibility that a variant of the device depicted in Figure 1 could be sized "much smaller" so as to be "portable" cannot support the conclusion that unit 14 in Figure 1 is necessarily hand-held. The Federal Circuit has been instructive on this point:

> It is true that the specification "does not have to provide *in haec verba* support for the claimed subject matter at issue." *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (Fed.Cir.2000) (citing *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570 (Fed.Cir.1996)). Nonetheless, the disclosure must clearly convey to one skilled in the art that the inventor was in possession of the invention. "Put another way, one skilled in the art, reading the . . . disclosure, must *immediately* discern the limitation at issue in the claims." *Id.* (citing *Waldemar Link, GmbH & Co. v. Osteonics Corp.*, 32 F.3d 556, 558 (Fed.Cir.1994)) (emphasis added). Immediacy is important because it guarantees that the insight belongs to the author of the specification and appears at once to the intelligent and educated reader. It is a different matter, however, if the language of the specification triggers an insight that belongs to the reader, who, having thought about the extent of what was actually disclosed by the specification, concludes, "This also could be done

> another way." In that circumstance, the reader is conceiving of an "obvious variant" of what is actually described, and that is not enough to satisfy the written description requirement. See *Lockwood*, 107 F.3d at 1572.

The Court finds that sizing unit 14 to be hand-held (as opposed to more generally "portable") qualifies as "an obvious variant" of the explicit disclosures in the specifications of the Pohl patent. An "obvious variant" of a patent incorporated by reference cannot provide support for an application amendment. To allow so many possible permutations of a given device to fall under the umbrella of inherent support would undermine the purpose of the written description requirement. Therefore, the Court finds that no reasonable juror could conclude that the Pohl patent provides support for the amendments made to the '021 patent application.

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Conclusion

The Court finds that the claims covering the improperly amended subject matter outlined above are invalid for new matter. Therefore, Defendant's Motion for Summary Judgment of Invalidity Based on New Matter (Dkt # 279) is GRANTED. Accordingly, all remaining motions are denied as moot.

Furthermore, the finding that independent claims 8, 20, and 25 are invalid for new matter compels the Court to reverse claim construction (b) in its Markman Order (Dkt.# 125) and consequently to reverse the finding of literal infringement in the Court's Order of September 29, 2004 (Dkt.# 162). Because Plaintiff's claims of infringement under 35 U.S.C. § 271(a) and (b) rely upon the inclusion of the invalid claims, the Court is also of the opinion that Plaintiff's claims for direct infringement and inducing infringement should be DISMISSED with prejudice.

It is so ORDERED.

A final judgment shall be issued separately.

Signed this 21st day of March, 2006.

s/ John D. Rainey
JOHN D. RAINEY
UNITED STATES DISTRICT JUDGE

APPENDIX C — MEMORANDUM AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF TEXAS, HOUSTON DIVISION DATED SEPTEMBER 30, 2004
(Re: Plaintiff's Motion for Summary Judgment on Infringement)

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

No. CIV.A.H-01-2484

NEUTRINO DEVELOPMENT CORPORATION,

Plaintiff,

v.

SONOSITE, INC.,

Defendant.

Sept. 30, 2004.

MEMORANDUM AND ORDER

RAINEY, District Judge.

Pending before the Court is Plaintiff's Motion for Summary Judgment on Infringement (Dkt.# 136). The Court, after reviewing the motion, the responses of the parties and the relevant law, is of the opinion that the motion should be GRANTED.

Appendix C

Factual and Procedural Background

This is an action for patent infringement brought by Neutrino Development Corporation ("Neutrino") against Sonosite, Inc. ("Sonosite"). Neutrino is the owner of United States Patent No. 6,221,021 ("the '021 patent"). Neutrino alleges that four devices manufactured and marketed by Sonosite, the Sonosite 180, SonoHeart, Sonosite 180 PLUS, and the SonoHeart PLUS, infringe on the '021 patent.

Richard T. Redano applied for a patent on the device in question on September 9, 1997. (Application Serial No. 08/926, 209).[1] The '021 patent, entitled "Method and Apparatus for Penile Hemodynamic Stimulation, Monitoring, and Drug Delivery Acceleration," resulted from that application. It describes a device for "stimulating and/or monitoring hemodynamic activity, such as blood flow, in a penis." *U.S. Patent No. 6,221,021* at col. 1, ll. 15-16.

Defendant Sonosite began as a division of ATL Ultrasound, Inc., and was spun off as a public company in April 1998. Sonosite unveiled its first public product in the realm of hand-carried ultrasound devices, the Sonosite 180, on May 17, 1999. Sonosite began selling the device in June 1999. In January 2000, Sonosite launched its second product, the SonoHeart. In April 2001, Sonosite launched a new generation of these two devices with its introduction of the SonoSite 180 PLUS and the SonoHeart PLUS.

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1. On May 20, 1999, Redano field a continuation in patent application, serial No. 09/315,867 which eventually issued as the '021 patent. In May 2000, Redano amended the pending '021 Patent Application to broaden its disclosure and expand the claims. The '021 patent was issued on April 24, 2001.

Appendix C

On July 24, 2001, Neutrino filed this action, alleging that Sonosite had illegally used Redano's invention and infringed the '021 patent. Sonosite answered the complaint on August 14, 2001, asserting that the '021 patent claims are not infringed and are invalid, and counterclaimed for declaratory judgment of non-infringement and invalidity.

On February 20, 2002, after extensive briefing, the Court held a one-day *Markman* hearing on claim construction. On October 9, 2002, the Court stayed all proceedings pending the Court's *Markman* and summary judgment rulings. The Court issued its claim construction on August 21, 2003. This motion for summary judgment was filed as a result of the Court's claim construction.

Summary Judgment Standard

Summary judgment is proper if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); *see also Christopher Village, LP v. Retsinas*, 190 F.3d 310, 314 (5th Cir.1999). "For any matter on which the non-movant would bear the burden of proof at trial . . . , the movant may merely point to the absence of evidence and thereby shift to the non-movant the burden of demonstrating by competent summary judgment proof that there is an issue of material fact warranting trial." *Transamerica Ins. Co. v. Avenell*, 66 F.3d 715, 718-19 (5th Cir.1995); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 323-25, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). To prevent summary judgment, the non-

movant must "respond by setting forth specific facts" that indicate a genuine issue of material fact. *Rushing v. Kansas City S. Ry. Co.*, 185 F.3d 496, 505 (5th Cir.1999).

When considering a motion for summary judgment, the Court must view the evidence in the light most favorable to the non-movant and draw all reasonable inferences in favor of the non-movant. *See Samuel v. Holmes*, 138 F.3d 173, 176 (5th Cir.1998); *Texas v. Thompson*, 70 F.3d 390, 392 (5th Cir.1995). "The court may not undertake to evaluate the credibility of the witnesses, weigh the evidence, or resolve factual disputes; so long as the evidence in the record is such that a reasonable jury drawing all inferences in favor of the nonmoving party could arrive at a verdict in that party's favor, the court must deny the motion." *Int'l Shortstop, Inc. v. Rally's, Inc.*, 939 F.2d 1257, 1263 (5th Cir.1991). However, the non-movant cannot avoid summary judgment by presenting only "conclusory allegations," or "unsubstantiated assertions," such as the bars allegations of a complaint, but must present sufficient evidence, such as sworn testimony in a deposition or affidavit, to create a genuine issue of material fact as to the claim asserted. *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 (5th Cir.1994) (en banc).

Patent cases are amenable to summary judgment as any other case when no genuine issue of material fact exists and the movant is entitled to judgment as a matter of law. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997); *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1576-77 (Fed.Cir.1989); *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1116 (Fed.Cir.1985).

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Analysis

Plaintiff Neutrino argues that Defendant's Sonosite 180, SonoHeart, Sonosite 180 PLUS and SonoHeart PLUS read on every claim in the '021 patent, thereby establishing literal infringement. In response, Sonosite argues that the patent is not infringed under the "reverse doctrine of equivalents."

Sonosite's argument centers on the idea that the accused devices are substantially different from the devices described in the original patent application. Sonosite supports this argument by asserting that the valid scope of the invention must be determined in accordance with the principles of 35 U.S.C. § 112 before the doctrine of equivalents can be applied. As stated by the Federal Circuit in *SRI International*, and clarified by that court in *Texas Instruments, Inc. v. U.S. Int'l Trade Comm'n*, 846 F.2d 1369, 1372 (Fed.Cir.1988), before the reverse doctrine of equivalents can be applied, there must be a finding of literal infringement. Sonosite has offered no evidence to suggest that the devices in question do not infringe the patent. Rather, Sonosite argues that a fact issue exists as to whether the accused devices are so far changed from the invention at suit that the reverse doctrine of equivalents applies. *See Sonosite's Response to the Motion for Summary Judgment on Infringement*, page 14. Thus it appears to the Court that Sonosite is conceding the issue of infringement by its argument in favor of the application of the reverse doctrine of equivalents. However, Neutrino still bears the burden of proving that the accused devices infringe on the patents.

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Infringement

The determination of patent infringement is a question of fact. *Karlin Tech., Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 974 (Fed.Cir.1999). With that in mind, the court must approach a summary judgment motion on the issue of infringement cautiously. *See SRI Int'l*, 775 F.2d at 1116. "Summary judgment is appropriate when it is apparent that only one conclusion as to infringement could be reached by a reasonable jury." *TechSearch, L.L.C. v. Intel Corp.*, 286 F.3d 1360, 1369 (Fed.Cir.2002).

Infringement analysis is a two-step process. *Seal-Flex, Inc. v. Athletic Track & Court Constr.*, 172 F.3d 836, 842 (Fed.Cir.1999); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed.Cir.1995), *aff'd*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). First, the claims in question must be construed as a matter of law; and second, the properly construed claims must be compared to the accused device or process. *Markman*, 52 F.3d at 976.

In a previous order, the Court construed the claims as follows:

1. "A transducer mounting assembly moveably connected to said body such that the distance between said assembly and said body can be adjusted by a user using only one hand"—An assembly sized to contain at least one ultrasound emitter or transducer, which is connected to the portable body such that a user of the apparatus can cause a change in the distance between the transducer mounting assembly and the portable body, using only one hand.

2. "A portable body sized to be hand held"—A body that is sized such that it can be held by hand and, so held, moved from one location to another.

3. "Ultrasound emitter"—At least one component, also known as a "transducer" or "emitter," and capable of emitting ultrasound energy.[2]

Therefore, the Court proceeds to the second step in the infringement analysis: comparing the claim, as construed by the Court, with the accused device. Infringement means that the accused device or process contains, either literally or under the doctrine of equivalents, "every limitation of the properly construed claim." *Seal-Flex*, 172 F.3d at 842.

Literal infringement exists when the accused device embodies each claim limitation precisely. *Kraft Foods, Inc. v. Int'l Trading Co.*, 203 F.3d 1362, 1370 (Fed.Cir.2000). If even one component of the claim is not found in the accused device exactly as recited in the claim, the claim does not "read on" the accused device and there can be no literal infringement. *See Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931 (Fed.Cir.1987). Infringement under the doctrine of equivalents requires that the accused product contain each limitation of the claim or its equivalent. *See Warner-Jenkinson*, 520 U.S. at 40, 117 S.Ct. 1040. "A claim element is equivalently present in an accused device if only

2. The Court held that the following terms did not need to be interpreted because they were unambiguous: 1) "mounted in," "mounted on," "housed within," and "top surface;" 2) "portable body comprising a top surface;" 3) "connected to" and "coupled to;" 4) "generating an instruction;" and 5) "display."

'insubstantial differences' distinguish the missing claim element from the corresponding aspects of the accused device." *Sage Prods., Inc. v. Devon Indus.*, 126 F.3d 1420, 1423 (Fed.Cir.1997). "Whether a component in the accused subject matter performs substantially the same function as the claimed limitation in substantially the same way to achieve substantially the same result may be relevant to this determination." *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 149 F.3d 1309, 1315 (Fed.Cir.1998).

Neutrino argues that the devices produced by Sonosite literally infringe on each of the patent claims. As support for this contention, Neutrino offers the testimony, in declaration form, of Richard Redano, the inventor of the '021 patent. In his declaration, Mr. Redano compares every element of the asserted claims of the '021 patent, as construed by the Court, to the Sonosite 180, Sonosite 180 PLUS, SonoHeart, and SonoHeart PLUS devices and concludes that every element is literally embodied in those devices.

Mr. Redano's declaration sets out in detail how each of the claims is infringed by the Sonosite devices. His declaration specifically references which portion of the Sonosite devices pertain to each claim. For example, with regard to the "portable body sized to be hand held" requirement, Mr. Redano, referencing pictures of the Sonosite devices produced in discovery, that "page P0216 and page P0240 the body is shown grasped in a user's hand. The body is sized such that it can be held by hand . . ." *See Declaration of Richard Redano*, attached as Exhibit A to Neutrino's Motion for Summary Judgment on Infringement, para. 15.

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Sonosite offers no evidence to contradict the testimony of Mr. Redano. Rather, Sonosite argues that the reverse doctrine of equivalents should apply in this case.

The Reverse Doctrine of Equivalents

The reverse doctrine of equivalents states that the doctrine may be used to restrict a claim and thus defeat a patentee's action for infringement where a device is "so far changed in principle from a patented article that it performs the same or similar function in a substantially different way, but nevertheless falls within the literal words of the claim." *Graver Tank & Mfg. v. Linde Air Prods. Co.*, 339 U.S. 605, 608-09, 70 S.Ct. 854, 94 L.Ed. 1097 (1950). The Federal Circuit, sitting *en banc*, phrased the inquiry as a single question in *SRI International v. Matsushita Electric Corporation*, stating that

> the reverse doctrine of equivalents...raises a fact question, determinable on inquiry into whether a product has been so far changed in principle that it performs the same or similar function in a substantially different way.

775 F.2d 1107, 1124 (Fed.Cir.1985) (en banc).

The Federal Circuit went on to say that though this inquiry differs from the inquiry under the doctrine of equivalents because literal infringement is inherently present in a reverse doctrine of equivalents case, it is nonetheless directed to a fact issue. *Id.* Therefore, when a patentee establishes literal infringement, "the accused infringer may

undertake the burden of going forward to establish the fact of non-infringement under the doctrine of reverse equivalents. If the accused infringer makes a prima facie case, the patentee, who retains the burden of persuasion on infringement, must rebut that prima facie case." *Id.*

Sonosite's argument centers on the idea that the accused devices are substantially different from the devices described in the original patent application. Sonosite supports this argument by asserting that the valid scope of the invention must be determined in accordance with the principles of 35 U.S.C. § 112 before the doctrine of equivalents can be applied. Sonosite furthers its contention by asserting that the enablement and the written description requirements of § 112 do not support a finding that the claimed invention enables or adequately describes a hand-held device. Rather, Sonosite asserts that a person skilled in the art of ultrasound would interpret the contents of the patent application, and the specifications contained therein, as describing a hand-held device that would connect to a standard ultrasound imaging system that is separate and distinct from the hand-held housing, and not an ultrasonography generator that would fit in a hand-held enclosure.

The Court, however, has already construed the claims of the patent to include a "body that is sized such that it can be held by hand . . ." The claim construction also indicates that the ultrasonography generator would be "mounted in said body." Additionally, the Federal Circuit made it clear in *SRI International* that the relevant test was whether the accused product was so far changed in principle that it performs the function of the *claimed invention* in a

substantially different way, not whether the accused device is so far changed in principle that it performs the function of the *patent application, prior to any amendments* in a substantially different way. *See SRI Int'l*, 775 F.2d at 1124. At that point, the court in *SRI International* looked to the evidence presented regarding the ways the two products functioned to determine whether they were substantially different. *Id.* The Court has found no case where a court has discussed the enablement or written description arguments made by the Defendant when discussing the reverse doctrine of equivalents.

Sonosite's summary judgment evidence in support of its contention that the reverse doctrine of equivalents applies in this case does not address the patented device. Rather, Sonosite attempts to create a fact issue on the doctrine of equivalents by comparing the accused devices to the language of the patent application prior to its amendment and prior to the issuance of the '021 patent. The Court finds, however, that this analysis is against the weight of the authority on this subject. Therefore, the Court declines to apply the reverse doctrine of equivalents in this case. Sonosite has not met its burden of establishing that the accused devices perform in a substantially different manner from the patented claim.

Appendix C

Conclusion

The Court finds that there is no evidence to support Sonosite's contention that the reverse doctrine of equivalents should be applied in this case. Therefore, because Sonosite does not raise a fact issue on the question of infringement, and the Court declines to apply the doctrine based on the facts presented by Defendant, Plaintiff's Motion for Summary Judgment on Infringement (Dkt.# 136) is GRANTED.

It is so ORDERED.

APPENDIX D — MEMORANDUM AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF TEXAS, HOUSTON DIVISION DATED SEPTEMBER 30, 2004
(Re: Defendant's Post-Markman Motion for Summary Judgment)

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

No. CIV.A.H-01-2484

NEUTRINO DEVELOPMENT CORPORATION,

Plaintiff,

v.

SONOSITE, INC.,

Defendant.

Sept. 30, 2004.

MEMORANDUM AND ORDER

RAINEY, District Judge.

Pending before the Court is Defendant's Post-Markman Motion for Summary Judgment based on Invalidity (Dkt.# 131). The Court, after reviewing the motion, the responses of the parties and the relevant law, is of the opinion that the motion should be DENIED.

Appendix D

Factual and Procedural Background

This is an action for patent infringement brought by Neutrino Development Corporation ("Neutrino") against Sonosite, Inc. ("Sonosite"). Neutrino is the owner of United States Patent No. 6,221,021 ("the '021 patent"). Neutrino alleges that four devices manufactured and marketed by Sonosite, the Sonosite 180, SonoHeart, Sonosite 180 PLUS, and the SonoHeart PLUS, infringe on the '021 patent.

Richard T. Redano applied for a patent on the device in question on September 9, 1997. (Application Serial No. 08/926, 209).[1] The '021 patent, entitled "Method and Apparatus for Penile Hemodynamic Stimulation, Monitoring, and Drug Delivery Acceleration," resulted from that application. It describes a device for "stimulating and/or monitoring hemodynamic activity, such as blood flow, in a penis." *U.S. Patent No. 6,221,021* at col. 1, ll. 15-16.

Defendant Sonosite began as a division of ATL Ultrasound, Inc., and was spun off as a public company in April 1998. Sonosite unveiled its first public product in the realm of hand-carried ultrasound devices, the Sonosite 180, on May 17, 1999. Sonosite began selling the device in June 1999. In January 2000, Sonosite launched its second product, the SonoHeart. In April 2001, Sonosite launched a new generation of these two devices with its introduction of the SonoSite 180 PLUS and the SonoHeart PLUS.

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1. On May 20, 1999, Redano field a continuation in patent application, serial No. 09/315,867 which eventually issued as the '021 patent. In May 2000, Redano amended the pending '021 Patent Application to broaden its disclosure and expand the claims. The '021 patent was issued on April 24, 2001.

Appendix D

On July 24, 2001, Neutrino filed this action, alleging that Sonosite had illegally used Redano's invention and infringed the '021 patent. Sonosite answered the complaint on August 14, 2001, asserting that the '021 patent claims are not infringed and are invalid, and counterclaimed for declaratory judgment of non-infringement and invalidity.

On February 20, 2002, after extensive briefing, the Court held a one-day *Markman* hearing on claim construction. On October 9, 2002, the Court stayed all proceedings pending the Court's *Markman* and summary judgment rulings. The Court issued its claim construction on August 21, 2003. This motion for summary judgment was filed as a result of the Court's claim construction.

Summary Judgment Standard

Summary judgment is proper if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); *see also Christopher Village, LP v. Retsinas*, 190 F.3d 310, 314 (5th Cir.1999). "For any matter on which the non-movant would bear the burden of proof at trial . . . , the movant may merely point to the absence of evidence and thereby shift to the non-movant the burden of demonstrating by competent summary judgment proof that there is an issue of material fact warranting trial." *Transamerica Ins. Co. v. Avenell*, 66 F.3d 715, 718-19 (5th Cir.1995); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 323-25, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). To prevent summary judgment, the non-

movant must "respond by setting forth specific facts" that indicate a genuine issue of material fact. *Rushing v. Kansas City S. Ry. Co.*, 185 F.3d 496, 505 (5th Cir.1999).

When considering a motion for summary judgment, the Court must view the evidence in the light most favorable to the non-movant and draw all reasonable inferences in favor of the non-movant. *See Samuel v. Holmes*, 138 F.3d 173, 176 (5th Cir.1998); *Texas v. Thompson*, 70 F.3d 390, 392 (5th Cir.1995). "The court may not undertake to evaluate the credibility of the witnesses, weigh the evidence, or resolve factual disputes; so long as the evidence in the record is such that a reasonable jury drawing all inferences in favor of the nonmoving party could arrive at a verdict in that party's favor, the court must deny the motion." *Int'l Shortstop, Inc. v. Rally's, Inc.*, 939 F.2d 1257, 1263 (5th Cir.1991). However, the non-movant cannot avoid summary judgment by presenting only "conclusory allegations," or "unsubstantiated assertions," such as the bare allegations of a complaint, but must present sufficient evidence, such as sworn testimony in a deposition or affidavit, to create a genuine issue of material fact as to the claim asserted. *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 (5th Cir.1994) (en banc).

Patent cases are amenable to summary judgment as any other case when no genuine issue of material fact exists and the movant is entitled to judgment as a matter of law. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997); *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1576-77 (Fed.Cir.1989); *SRI Int'l v. Matsushita Elec. Corp. of Am.*; 775 F.2d 1107, 1116 (Fed.Cir.1985).

Appendix D

Analysis

Defendant challenges the validity of the '021 patent by asserting that the invention was on sale in the country more than one year prior to the date of the patent and thus the patent is invalid because it violates the on-sale bar of 35 U.S.C. § 102(b). Additionally, Defendant challenges the validity of the patent by asserting that the claims of the patent read on a prior art product, a Diasonics Ultrasound Model Inpact VFI, also known as the Compact System ("Compact System"), and is thus anticipated under 35 U.S.C. § 102(b).

Under 35 U.S.C. § 282, a patent is presumed valid and an attack on its validity requires proof of facts by "clear and convincing evidence or its equivalent, by whatever form of words it may be expressed." *American Hoist & Derrick Co. v. Sowa & Sons*, 725 F.2d 1350, 1360 (Fed.Cir.), *cert. denied*, 469 U.S. 821, 105 S.Ct. 95, 83 L.Ed.2d 41 (1984). The "clear and convincing" standard of proof of facts is an intermediate standard which lies somewhere between "beyond a reasonable doubt" and a "preponderance of the evidence." *Addington v. Texas*, 441 U.S. 418, 425, 99 S.Ct. 1804, 60 L.Ed.2d 323 (1979). Although not susceptible to precise definition, "clear and convincing evidence" has been described as evidence which produces in the mind of the trier of fact "an abiding conviction that [the] truth of the factual contentions are 'highly probable.' " *Colorado v. New Mexico*, 467 U.S. 310, 316, 104 S.Ct. 2433, 81 L.Ed.2d 247 (1984).

Appendix D

On-Sale Bar

Under § 102(b), "[a] person shall be entitled to a patent unless . . . the invention was . . . on sale in this country, more than one year prior to the date of the application for the patent in the United States." 35 U.S.C. § 102(b) (2000). A § 102(b) determination is a conclusion of law based on underlying findings of fact. *Linear Tech. Corp. v. Micrel, Inc.*, 275 F.3d 1040, 1047 (Fed.Cir.2001). A two pronged test governs the application of the on-sale bar: "First, the product must be the subject of a commercial offer for sale . . . Second, the invention must be ready for patenting." *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67, 119 S.Ct. 304, 142 L.Ed.2d 261 (1998). Sonosite's motion for summary judgment focuses on the first prong of this test.

Although the standard for determining what constitutes an offer to sell sufficient to raise the on sale bar had been subject to come confusion, the Federal Circuit clarified the standard in *Group One Limited v. Hallmark Cards*, 254 F.3d 1041 (Fed.Cir.2001). In *Group One*, the Federal Circuit held that "[o]nly an offer which rises to the level of a commercial offer for sale, one which the other party could make into a binding contract by simple acceptance (assuming consideration), constitutes an offer for sale under § 102(b)." *Id.* at 1048 (concluding that the need for national uniformity in patent law requires the application of federal common law). To determine if the offer is sufficiently definite, one must examine the language of the proposal in accordance with the principles of general contract law. *Id.* at 1048. Because this issue is governed by federal common law, an important relevant source of general contract law for determining

whether a "communication or series of communications rises to the level of a commercial offer for sale" is the Uniform Commercial Code ("UCC"). *Id.* at 1047; *see also Univ. of Colo. Found., Inc., v. Am. Cyanamid Co.*, 196 F.3d 1366, 1372 (Fed.Cir.1999). Notably, an offer for sale does not have to be accepted to implicate the on-sale bar. *UMC Elecs. Co. v. United States*, 816 F.2d 647, 653 (Fed.Cir.1987) (overruled on other grounds by *Pfaff*, 525 U.S. 55, 119 S.Ct. 304, 142 L.Ed.2d 261 (1998)).

Sonosite asserts that a device embodying each claim of the disputed patent was on sale prior to September 9, 1996, the critical date for determining whether the on-sale bar applies. Specifically, Sonosite asserts that Diasonics Ultrasound Inc. ("Diasonics") advertised and sold its Impact VFI portable ultrasound imaging device, also known as the Compact System ("Compact System") prior to the critical date. To support this contention, Sonosite relies on the declaration of David Sherman, an employee of Sonosite who was previously employed by Diasonics Ultrasound. Sherman's declaration states that he was "personally involved in the sales process for the Impact VFI portable ultrasound imaging device, also known and marketed as the Compact VFI and the Diasonics Compact System, which was sold by Diasonics and manufactured by Ausonics Pty. Ltd." *Declaration of David Sherman, attached to Sonosite's Motion for Summary Judgment*, para. 12. Sherman goes on to state that "Diasonics first placed this device on sale in the United States prior to April 1996." Mr. Sherman also states that he has reviewed the advertising literature (the Diasonics brochure)and asserts that it was "printed in April 1996 and that it was widely distributed to potential customers of the device." *Id.* at para. 13.

The Federal Circuit, however, has made it clear that "uncorroborated oral testimony, particularly that of interested persons recalling long past events, does not, of itself, provide the clear and convincing evidence required to invalidate a patent . . ." *Woodland Trust v. Flowertree Nursery*, 148 F.3d 1368, 1369 (Fed.Cir.1998).

As supporting documentation, Sonosite has provided a copy of a brochure created by Diasonics, which describes the Compact System. The only date information on the brochure is a notation on the last page which reads "Diasonics Ultrasound Pt. No. 925-00001-00 Rev C 4/96." This is the only possible corroboration on the document that suggests that the device was on sale on or before April of 1996. This evidence is not enough, however, to trigger the on sale bar. *See Lacks Indus., Inc. v. McKechnie Vehicle Components USA, Inc.*, 322 F.3d 1335 (requiring a formal offer under principles of contract law before the on-sale bar is implicated). At best, this date corroborates Mr. Sherman's testimony that the brochure was printed in April of 1996.

Thus, the Court finds that Sonosite does not provide sufficient evidence to corroborate Sherman's testimony. Rather, Sonosite asks the Court to draw inferences from a date on a brochure and the testimony of an individual who does not provide a date certain for Diasonics's sale of the Compact System, but rather testifies that it was on sale "before April 1996." The Court finds that this information, without something more definite to show that the device was actually on sale, fails to meet the clear and convincing evidence standard necessary to trigger the on-sale bar. *See Intel Corp. v. U.S. Int'l Trade Comm'n*, 946 F.2d 821

(Fed.Cir.1991) (holding that the Court would have to "engage in extensive inference drawing to conclude" that the product in question had actually been sold prior to the critical date merely because protypes had been given to salesmen with instructions to sell them).

Anticipation.

Sonosite further argues that the Diasonics device anticipates every claim of the '021 patent. Although the question of whether a device was on-sale before the critical date is a question of law determined by underlying factual issues, anticipation is a question of fact. *Compare Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1186 (Fed.Cir.1993) (holding that the on sale bar was a question of law amenable to summary judgment where there were no underlying material facts in issue) *with Advanced Display Sys. Inc. v. Kent State Univ.*, 212 F.3d 1272, 1281 (Fed.Cir.2000) (holding that anticipation is a question of fact (internal citation omitted)). To make such a finding on summary judgment, the Court must determine that no facts material to the question are disputed; or that even if all material factual inferences are drawn in favor of the non-movant, there is no reasonable basis on which the non-movant can prevail. *Cooper v. Ford Motor Co.*, 748 F.2d 677, 679 (Fed.Cir.1984).

Section 102(b) provides that "a person shall be entitled to a patent unless the invention was patented or described in a printed publication . . . more than one year prior to the date of publication." 35 U.S.C. § 102(b) (2000). Accordingly, invalidity by anticipation requires that the four corners of a

single, prior art document describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could produce the invention without undue experimentation. *See Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347 (Fed.Cir.1999). Material not explicitly contained in the single, prior art document may still be considered for purposes of anticipation if that material is incorporated by reference into the document. *See Ultradent Prods., Inc. v. Life-Like Cosmetics, Inc.*, 127 F.3d 1065, 1069 (Fed.Cir.1997) (holding that material incorporated by reference into a document may be considered in an anticipation determination). Additionally, extrinsic information may be considered to explain the disclosure of a reference. The role of extrinsic evidence is to educate the decision-maker to what the reference meant to persons of ordinary skill in the field of the invention, not to fill gaps in the reference. *See Studiengesellschaft Kohle, m.b.H. v. Dart Indus., Inc.*, 726 F.2d 724, 727 (Fed.Cir.1984) (although additional references may serve to reveal what a reference would have meant to a person of ordinary skill, it is error to build "anticipation" on a combination of these references). If it is necessary to reach beyond the boundaries of a single reference to provide missing disclosure of the claimed invention, the proper ground is not § 102 anticipation, but § 103 obviousness. *Scripps Clinic and Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1577 (Fed.Cir.1991).

Evaluating an anticipation claim requires a two step analysis. The first step of an anticipation analysis is claim construction. *See Key Pharms. v. Hercon Labs. Corp.*, 161 F.3d 709, 714 (Fed.Cir.1998). The Court, after hearing evidence and testimony at a *Markman* hearing, issued its

claim construction on August 20, 2003. In its order, the Court construed the '021 patent as follows:

1. "A transducer mounting assembly moveably connected to said body such that the distance between said assembly and said body can be adjusted by a user using only one hand"-An assembly sized to contain at least one ultrasound emitter or transducer, which is connected to the portable body such that a user of the apparatus can cause a change in the distance between the transducer mounting assembly and the portable body, using only one hand.

2. "A portable body sized to be hand held"-A body that is sized such that it can be held by hand and, so held, moved from one location to another.

3. "Ultrasound emitter"-At least one component, also known as a "transducer" or "emitter," and capable of emitting ultrasound energy.[2]

The second step of the analysis involves a comparison of the construed claim to the prior art. *See Key Pharms.*, 161 F.3d at 714. To be anticipating, a prior art reference must disclose "each and every limitation of the claimed invention[,] . . . must be enabling[,] and [must] describe . . . [the]claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the field of the

2. The Court held that the following terms did not need to be interpreted because they were unambiguous: 1) "mounted in," "mounted on," "housed within," and "top surface;" 2) "portable body comprising a top surface;" 3) "connected to" and "coupled to;" 4) "generating an instruction;" and 5) "display."

invention." *Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1346 (Fed.Cir.2000)(quoting *In re Paulsen*, 30 F.3d 1475, 1478-79 (Fed.Cir.1994)). If there is a genuine issue of material fact relevant to any one of these factors, summary judgment is not proper. *Id.*

Sonosite's motion for summary judgment argues that the Diasonics device discloses each of the limitations of claims 8, 11, 12, 13, 20, 21, and 23-27 of the '021 patent as construed by the Court. To support this contention, Sonosite attached as exhibits the Diasonics brochure, the declaration of David Sherman, the declaration of Robert Isackson, and a transcript of the testimony of Jens Quistgaard from the *Markman* hearing. Sonosite also attached a "detailed claims chart" outlining the ways in which the Diasonics device anticipates each claim of the patented device. *See Sonosite's Motion for Summary Judgment, Exhibit 1.*

Neutrino objects to these supporting documents as being hearsay, uncorroborated, lacking in foundation, speculation, and wholly based on interested testimony. With regard to the declarations of Isackson, Sherman and Quistgaard and the testimony of Quistgaard from the *Markman* hearing, Neutrino also objects that they are providing expert opinions without having been designated as experts. First, with respect to the Diasonics brochure, Neutrino questions its authenticity as well as arguing that it contains hearsay and that it is uncorroborated. The Court ruled on this same issue in an order dated September 24, 2002. In that order, the Court held that the brochure was not hearsay because it is a legally operative document. *See Court's Order on Plaintiff Neutrino's Motion to Strike Inadmissible Exhibits* (Dkt.# 122)

(citing *Stuart v. UNUM Life Ins. Co. of Am.*, 217 F.3d 1145, 1154 (9th Cir.2000)). The Court also held that the document "need only be authenticated to be admissible." *Id.* citing *Kepner-Tregoe, Inc. v. Leadership Software, Inc.*, 12 F.3d 527, 540 (5th Cir.1994). In the Court's opinion, the declaration of David Sherman authenticates the brochure when he states that he has reviewed the advertising literature (the Diasonics brochure) and can "confirm that it accurately depicts the Diasonics Impact VFI device," and "that it was printed in April 1996 . . ." *See Declaration of David Sherman, attached to Sonosite's Post-Markman Motion for Summary Judgment based on Invalidity*, para. 12. Second, with regard to the "claims chart," Neutrino objects that the chart is uncorroborated and wholly based on interested testimony. The Court notes, however, that Neutrino provides a chart of its own to detail how and why the claims are not anticipated by the Diasonics device. Although Neutrino's chart is different from Sonosite's in that Neutrino's chart contains references to both interested and purportedly uninterested testimony, this is a credibility determination to be made by the finder of fact, not the Court. Finally, with respect to the declarations of Isackson, Sherman and Quistgaard, and the Quistgaard testimony, Neutrino objects that these statements offer expert opinions although the individuals giving them have not been designated as experts. The Court finds these to be substantially similar to the declarations of Douglas Beall and Richard Redano, which are attached to Neutrino's response to the Motion for Summary Judgment and are used by Neutrino to support its contention that the patent is not invalid. Although the Court notes that neither side has designated experts, the Court also notes that neither side is precluded from submitting the opinions of lay witnesses, so

long as those opinions are limited to "those opinions which are (a) rationally based on the perception of the witness; (b) helpful to a clear understanding of the witness' testimony or the determination of a fact in issue, and (c) not based on scientific, technical, or other specialized knowledge within the scope of Rule 702." *Fed.R.Evid.* 701. To the extent that any of the declarations or transcript testimony rises to the level of expert testimony, the Court will disregard those portions of the declarations or transcript testimony. The majority of the declarations' contents, however, are admissible as perceptions of the witnesses or as being helpful to a clear understanding of the witnesses' testimony and the determination of a fact in issue. Therefore, the Court will allow the declarations to be used as summary judgment evidence.

Having reviewed all of the documentation discussed above, the Court believes that a fact issue exists on the issue of anticipation. The Court cannot reconcile the testimony of Dr. Quistgaard with that of Dr. Beall. Dr. Quistgaard's testimony, coupled with that of Mr. Sherman, is that the Diasonics device anticipates each claim of the '021 patent. Dr. Beall, on the other hand, asserts that the Diasoncs device does not anticipate any of the claims of the '021 patent. For example, with regard to the claim that the device contain "a body that is sized such that it can be held by hand, and so held, moved from one location to another," Dr. Quistgaard testified that the Diasonics device was capable of being picked up by someone such as himself and moved from one location to another. *See Testimony of Jens Quistgaard, attached as Exhibit R to the Declaration of Robert Isackson*, page 14, lines 8-10. Thus, Dr. Quistgaard believes that the

claims relating to the device being hand-held are anticipated by the Diasonics device. Dr. Beall's declaration states, however, that from his review of the Diasonics literature and his observations of the device, the Diasonics device would be too large and too heavy for someone such as himself to hold the body of the device by hand and move it from one location to another. *See Declaration of Douglas Beall attached to Plaintiff's Response to the Motion for Summary Judgment*, page 4, paragraph 9 & 10. Thus, Dr. Beall believes that the Diasonics device does not anticipate the hand-held portions of the '021 patent. The portability of the device is an issue that occurs in independent claim numbers 8, 20, and 25. The parties' witnesses have equally competing views on issues relating to the transducers, the ability of an operator of the Diasonics device to change the distance between the transducer mounting assembly and the portable body using only one hand, and whether the Diasonics device actually contains "at least two ultrasound emitters" as required by the '021 patent. Thus, the Court is faced with conflicting testimony regarding virtually every aspect of the '021 patent. Whether the Diasonics device anticipates each of the claims in the patent, based on the observations of the parties' competing witnesses, is a question for the trier of fact, rather than the Court, to decide. Therefore, the Court finds that summary judgment is inappropriate.

Appendix D

Conclusion

The Court finds that there are fact issues surrounding the on-sale bar and the issue of anticipation. Therefore, Defendant's Post-Markman Motion for Summary Judgment based on Invalidity (Dkt. # 131) is DENIED.

It is so ORDERED.

APPENDIX E — OPINION OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF TEXAS, HOUSTON DIVISION DATED JANUARY 23, 2006

UNITED STATES DISTRICT COURT
S.D. TEXAS
HOUSTON DIVISION

No. CIV.A. H-01-2484.

Jan. 23, 2006.

NEUTRINO DEVELOPMENT CORPORATION,

Plaintiff,

v.

SONOSITE, INC.,

Defendant.

MEMORANDUM AND ORDER

RAINEY, District Judge.

Pending before the Court are Neutrino Development Corporation's ("Neutrino") Motion to Exclude Testimony of Defendant SonoSite's Expert Witness Joan Baker (Dkt. # 258), Neutrino's Motion to Exclude Testimony of Defendant SonoSite's Expert Witness Donald W. Baker (Dkt.# 259), Neutrino's Motion to Exclude Testimony of Defendant SonoSite's Expert Witness Dr. Don L.

Berardinucci (Dkt.# 260), Neutrino's Motion to Exclude Testimony of Defendant SonoSite's Expert Witness Cameron Weiffenbach (Dkt.# 261), Neutrino's Motion to Exclude Testimony of Defendant SonoSite's Expert Witness Jens U. Quistgaard (Dkt.# 262), Neutrino's Motion to Exclude Testimony of Defendant SonoSite's Expert Witness Jens U. Quistgaard on Lack of Infringement by SonoSite's Products (Dkt.# 266), Neutrino's Motion to Exclude Testimony of Defendant SonoSite's Expert Witness Lauren S. Pflugrath (Dkt.# 267), and Neutrino's Motion to Exclude, or In Limine, the Testimony of Stephen M. Graham (Dkt. # 343). The Court, having reviewed the motions, the responses of the parties, and the applicable law, is of the opinion that Plaintiff's motions (Dkt.#258, 267, and 343) should be DENIED, Plaintiff's motion (Dkt.# 260) should be GRANTED, and Plaintiff's motions (Dkt.#259, 261, 262, and 266) should be GRANTED in part and DENIED in part.

Factual and Procedural Background

This is an action for patent infringement brought by Neutrino Development Corporation ("Neutrino") against Sonosite, Inc. ("Sonosite"). Neutrino is the owner of United States Patent No. 6,221,021 ("the '021 patent"). Neutrino alleges that four devices manufactured and marketed by Sonosite, the Sonosite 180, SonoHeart, Sonosite 180 PLUS, and the SonoHeart PLUS, infringe on the '021 patent.

Richard T. Redano applied for a patent on the device in question on September 9, 1997. (Application Serial No. 08/926, 209). The '021 patent, entitled "Method and Apparatus for Penile Hemodynamic Stimulation, Monitoring, and Drug

Delivery Acceleration," resulted from that application. It describes a device for "stimulating and/or monitoring hemodynamic activity, such as blood flow, in a penis." *U.S. Patent No. 6,221,021* at col. 1, ll. 15-16.

Defendant Sonosite began as a division of ATL Ultrasound, Inc., and was spun off as a public company in April 1998. Sonosite unveiled its first public product in the realm of hand-carried ultrasound devices, the Sonosite 180, on May 17, 1999. Sonosite began selling the device in June 1999. In January 2000, Sonosite launched its second product, the SonoHeart. In April 2001, Sonosite launched a new generation of these two devices with its introduction of the SonoSite 180 PLUS and the SonoHeart PLUS.

On July 24, 2001, Neutrino filed this action, alleging that Sonosite had illegally used Redano's invention and infringed the '021 patent. Sonosite answered the complaint on August 14, 2001, asserting that the '021 patent claims are not infringed and are invalid, and counterclaimed for declaratory judgment of non-infringement and invalidity.

On February 20, 2002, after extensive briefing, the Court held a one-day *Markman* hearing on claim construction. On October 9, 2002, the Court stayed all proceedings pending the Court's *Markman* and summary judgment rulings. The Court issued its claim construction on August 21, 2003. Subsequently, the Court granted Neutrino's Motion for Summary Judgment on Infringement (Dkt.# 136) finding that Sonosite's devices literally infringed the '021 patent and the reverse doctrine of equivalents was not applicable (Dkt.# 162). Consequently, Sonosite's case for trial focuses on the

invalidity of the '021 patent, which requires expert testimony about the '021 patent and certain prior art. Neutrino has objected to the testimony of the above-named seven Sonosite experts.

Expert Testimony Standard

Federal Rule of Evidence 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

This "imposes a special obligation upon a trial judge to 'ensure that any and all scientific testimony' . . . is not only relevant, but reliable." *Kumho Tire Co., Ltd. v. Carmichael,* 526 U.S. 137, 147, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999) (quoting *Daubert v. Merrell Dow Pharms., Inc.,* 509 U.S. 579, 589, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993)). The expert testimony must be relevant, not simply in the sense that all testimony must be relevant under Federal Rule of Evidence 402, but also in the sense that the expert's proposed opinion is based on a valid scientific inquiry. *Daubert,* 509 U.S. at 592, 113 S.Ct. 2786.

Appendix E

The Supreme Court has provided five non-exclusive factors to consider when assessing whether the methodology upon which an expert rests his opinion is scientifically reliable. These factors are (1) whether the expert's theory can be or has been tested, (2) whether the theory has been subject to peer review and publication, (3) the known or potential rate of error of a technique or theory when applied, (4) the existence and maintenance of standards and controls, and (5) the degree to which the technique or theory has been generally accepted in the scientific community. *Daubert,* 509 U.S. at 593-94, 113 S.Ct. 2786; *Burleson v. Texas Dept. of Criminal Justice,* 393 F.3d 577 (5th Cir.2004). The test for determining reliability is flexible and can adapt to the particular circumstances underlying the testimony at issue. *Kumho Tire,* 526 U.S. at 150-51, 119 S.Ct. 1167. The party seeking to have the district court admit expert testimony must demonstrate by a preponderance of the evidence that the expert's findings and conclusions are reliable, but need not show that the expert's findings and conclusions are correct. *Moore v. Ashland Chem., Inc.,* 151 F.3d 269, 276 (5th Cir.1998).

Discussion

I. Joan Baker

Ms. Baker's testimony pertains to whether certain amendments made to the '021 patent specification constituted a "new matter" and were therefore improperly included under the patent.[1] For such an amendment to be properly included

1. *See* Sonosite's Exhibit 12. Amendments made via letter of May 4, 2000 and letter of November 14, 2000.

it must be inherently supported in the original patent application. 35 U.S.C. § 132. That is, a person of ordinary skill in the art could have looked at the patent application as of the filing date and determined that the claimed invention included the later-claimed subject matter. *TurboCare Div. of Demag Delaval Turbomach. Corp. v. Gen. Elec. Co.*, 264 F.3d 1111, 1118-19 (Fed.Cir.2001). Neutrino objects to Ms. Baker's testimony on three grounds: (1) Ms. Baker is not qualified to give expert opinions on the "ordinary level of skill in the art" for the '021 patent; (2) Ms. Baker has failed to determine what "one of ordinary skill in the art" would recognize from the initial disclosures of the '021 patent; and (3) Ms. Baker's opinions are conclusory and are not supported by any of the reliability factors recognized under *Daubert*.[2]

Sonosite opposes Neutrino's contention that Ms. Baker's qualifications are wanting on the grounds that she is a "pioneer" in the field of medical ultrasound and has extensive experience with the use and operation of diagnostic medical ultrasound devices.[3] The Court acknowledges that Ms. Baker's resume and professional experience support Sonosite's characterization of her qualifications. However, Ms. Baker's qualifications must allow her to offer opinions from the perspective of "one of ordinary skill in the art." The appropriate level of ordinary skill in the art is a complex factual inquiry within an abstract legal standard. *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed.Cir.1991). Although the finder of fact will ultimately decide the level

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2. Dkt. # 258, p. 2.

3. Dkt. # 300, at 1-4.

of ordinary skill in the art, the Court must determine the relevant art area as a matter of law in order to determine whether particular experts are qualified under *Daubert*. Courts have long acknowledged the difficulty of this task. Judge Learned Hand, writing for the Second Circuit Court of Appeals before the regional appellate courts were rescued from such matters in 1982, quipped that, "[w]hen all is said, we are called upon imaginatively to project this act of discovery against an hypostatized average practitioner, acquainted with all that has been published and all that has been publicly sold. If there be an issue more troublesome, or more apt for litigation than this, we are not aware of it." *Harries v. Air King Products Co.*, 183 F.2d 158, 162 (2d Cir.1950).

The "new matter" defense at bar requires the hypothetical person of ordinary skill in the art to be able to construe the '021 patent application and thereby understand what comprises the claimed invention. The specific issue at bar is whether the hand-held nature of the ultrasonography generator claimed in the amendment was inherent in the original patent application. The Court finds that the relevant art area for making this determination is the "designing, testing and building" of medical ultrasound devices.[4] The law does not require an expert opining from the perspective of "one of ordinary skill in the art" to have the same qualifications as the inventor or even be an inventor herself. *See Orthopedic Equip. Co. v. All Orthopedic Appliances*, 707 F.2d 1376, 1382 (Fed.Cir.1983). But it does require that she is sufficiently qualified to construe the patent and understand

4. Sonosite's Exhibit 10. This formulation of the relevant art area clarifies the Court's broader formulation in Dkt. # 325, p. 6.

the design and components of the claimed invention as one with ordinary skill in the art of designing, testing, and building medical ultrasound devices.

Ms. Baker's report and curriculum vitae establish that her qualifications are in the relevant art area. Ms. Baker's experience consulting on the design features of prototype medical ultrasound devices and considering the ergonomic aspects of medical ultrasound devices qualify her to opine about what design features would be inherently understood from the description of the ultrasonography generator in the original patent application.[5] The ability of a user to hold a component of the device in his hand is specifically an ergonomic issue. Whether such an ergonomic feature is inherently described in the original patent application is something about which Ms. Baker is qualified to testify under *Daubert.*

Neutrino also challenges Ms. Baker's testimony on the grounds that she has not properly resolved the skill level of one of "ordinary skill in the art." Neutrino argues that, because Ms. Baker has failed to determine the level of ordinary skill in the art, her opinions are irrelevant because they are not offered from the legally requisite perspective. "In determining [the level of ordinary skill in the art], the [trier of fact] may consider various factors including 'type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field.' " *In re GPAC Inc.*, 57 F.3d 1573,

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5. Sonosite's Exhibit 12, pp. 1-3.

1579 (Fed.Cir.1995) (*quoting Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962-63 (Fed.Cir.1986)). Neutrino objects to Ms. Baker's failure to establish the level of skill she applied to her analysis through the investigation of these factors. In order for Ms. Baker's testimony to be relevant to the issue of "new matter," Sonosite must establish that she has knowledge of the level of ordinary skill in the art and that she has applied that perspective to her testimony. Any disagreement between the parties about what constitutes the level of ordinary skill would present a fact issue to be resolved by the jury. However, Neutrino claims that Ms. Baker has failed to offer *any* factual basis that could be evaluated by the jury.[6] The Court disagrees. In her deposition, Ms. Baker testified that she considered the level of ordinary skill in the art to be a person who "has been trained and passed one's credentialing examinations . . ."[7] This statement is sufficient to allow the jury to determine whether this is the appropriate level of ordinary skill in art. Neutrino's disagreement with Ms. Baker's formulation of the level of ordinary skill goes to the weight of her testimony, not to its admissibility.

Finally, Neutrino objects to the reliability of Ms. Baker's testimony on the grounds that (1) she failed to consider all the patents incorporated by reference in the '021 patent, (2) she did not understand the terms "ultrasound generator" and "ultrasonography generator," (3) she only considered one embodiment of the Pohl patent, and (4) she incorrectly concludes that it would require 4 hands to operate the device

6. Dkt. # 258, pp. 4-6.

7. Sonosite's Exhibit 15, at 59.

described in the '021 patent. Neutrino's allegation that Ms. Baker failed to consider all of the patents incorporated by reference in the '021 patent is based on her admission that she did not use United States Patent No. 5,565,466 disclosed to Gioco et al. ("the '466 patent") in preparing her report.[8] Neutrino argues that this admitted omission renders her evaluation of the '021 patent incomplete and therefore unreliable under *Daubert*. Materials incorporated by reference in a patent are effectively part of the patent as though they were explicitly included in their entirety within the patent document. *Adv. Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed.Cir.2000). Ambiguous terms within the patent can sometimes be interpreted in light of disclosures made in the materials incorporated by reference. The "new matter" issue relevant to Ms. Baker's testimony focuses on the ambiguity of the term "ultrasonography generator" in the '021 patent. Proper evaluation of that term would require Ms. Baker to interpret it in light of disclosures made in the patents incorporated by reference in the '021 patent. Ms. Baker explains in her deposition testimony that she did not consider the '466 patent and did not include it with her report because its disclosures were irrelevant to opinions about the size of the ultrasonography generator in the '021 patent. The '466 patent discloses a method for enhancing sexual stimulation by introducing a vasodilator agent into circulation to improve blood flow to the genital region. The '466 patent does not involve or discuss medical ultrasound devices or disclose any information that could have informed Ms. Baker's conclusions about the size of the ultrasonography generator described in the '021 patent.

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8. Dkt. # 258, at 15.

Therefore, the Court finds that Ms. Baker's exclusion of the '466 patent from her report was appropriate under the circumstances and does not compromise the reliability of her testimony.

Neutrino also argues that Ms. Baker admitted in her deposition testimony that she did not understand the terms "ultrasound generator" and "ultrasonography generator" and therefore her testimony about the meaning of these terms is uninformed and unreliable.[9] Ms. Baker explained in her report that the "terms 'Ultrasonography Generator' and 'Ultrasound Generator' are not terms typically used in the field of ultrasound, and have no special meaning."[10] Similarly, Ms. Baker's subsequent deposition testimony that she could not be sure what Mr. Redano meant by those terms in the '021 patent simply indicated that those terms did not have meaning in common usage independent of the '021 patent. Nothing in Ms. Baker's report or deposition testimony indicates that her understanding of the those terms was deficient. Ms. Baker's specific understanding of the meaning of those terms is a matter ripe for cross-examination.

Neutrino also challenges Ms. Baker's testimony on the grounds that her report only considered one embodiment of United States Patent No. 5,578,060 disclosed to Pohl et al. ("Pohl patent"). Neutrino has taken the position that the original '901 patent application inherently disclosed a portable, hand-held ultrasonography generator by

9. *Id.* at 16.

10. Sonosite's Exhibit 12, p. 4.

incorporating by reference the Pohl patent. Ms. Baker concluded in her report that the Pohl patent did not describe a hand-held device.[11] Neutrino challenges the reliability of Ms. Baker's conclusion on the grounds that she failed to evaluate the entirety of the Pohl patent. Sonosite argues that Neutrino's challenge goes to the weight of Ms. Baker's testimony, not to its admissibility. The Court agrees. The reliability inquiry under *Daubert* asks the Court to consider the methodology the expert employed to reach her conclusion, not the accuracy of the conclusion itself. *Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 276 (5th Cir.1998). Ms. Baker's report discusses several aspects of the Pohl patent and specifically considers Mr. Redano's claims about the Pohl patent. Neutrino presents no evidence that Ms. Baker's evaluation of the Pohl patent was deficient for purposes of determining whether or not that patent disclosed a hand-held component equivalent to the ultrasonography generator in the '901 and '021 patent applications. Sonosite suggests, and the Court agrees, that the accuracy of Ms. Baker's conclusions about the Pohl patent are a matter ripe for cross-examination and not appropriate grounds for exclusion.

Finally, Neutrino challenges the reliability of Ms. Baker's testimony on the grounds that her report improperly concludes that four hands would be required to operate the device disclosed in the '021 patent. Neutrino objects to Ms. Baker's reliance on "the originally filed application from which the '021 Patent claims priority."[12] Neutrino contends

11. *Id.* at 8-10.

12. Dkt. # 258, at 20.

that the appropriate focus should have been the "invention," which it defines as "the claims of the patent."[13] However, the Federal Circuit has explained that "[t]he written description requirement and its corollary, the new matter prohibition of 35 U.S.C. § 132, both serve to ensure that the patent applicant was in full possession of the claimed subject matter on the application filing date." *TurboCare*, 264 F.3d at 1118. New claims and any other added material must find support in the *original* specification. Therefore, the Court finds that Ms. Baker properly focused her "new matter" analysis on the specification in the original patent application.

As for Neutrino's disagreement with Ms. Baker over the numbers of hands required to hold different components and turn different knobs, the Court finds that such a factual controversy is more appropriate for cross-examination. Therefore, the Court finds that Ms. Baker's testimony is admissible under *Daubert*.

II. Donald W. Baker

Mr. Baker's testimony pertains to whether the '021 patent would have enabled a person of ordinary skill in the art at the time the patent application was filed to make and use the claimed invention without undue experimentation. 35 U.S.C. § 112; *Adang v. Fischhoff*, 286 F.3d 1346, 1355 (Fed.Cir.2002); *In re Wands*, 858 F.2d 731, 737 (Fed.Cir.1988). Neutrino objects to Mr. Baker's testimony on five grounds: (1) Mr. Baker's underlying expertise was out-dated at the time the '021 patent was filed; (2) Mr. Baker

13. *Id.* at 21.

has demonstrated no knowledge of the level of ordinary skill in the art; (3) Mr. Baker's "real world feasibility" testimony is irrelevant and unreliable; (4) Mr. Baker failed to exclusively focus on the claims of the '021 patent; and (5) Mr. Baker failed to properly consider the patents incorporated by reference in the '021 patent.

Neutrino challenges Mr. Baker's qualifications to testify from the perspective of one of ordinary skill in the art at the time the patent application was filed on the grounds that he had been retired from the field for 12 years at the time of the filing in 1997. Mr. Baker's curriculum vitae confirms that he held his last professional position in the field in 1983. Furthermore, during his deposition, Mr. Baker conceded that "many advances" in medical ultrasound technology and in the miniaturization of electronic components used in commercial products had taken place in the 12-year period between his last professional position in the field and the date the '021 patent was filed.[14] Sonosite contends that Mr. Baker remained current in the field through teaching, consulting, and reading professional journals and was thereby knowledgeable about the level of ordinary skill in the art in 1997. Sonosite further argues that Mr. Baker's retirement from the field is not sufficient to disqualify him as an expert. The Court agrees that the simple fact that Mr. Baker was retired in 1997 does not, in and of itself, disqualify his testimony; however, the relevant inquiry under the enablement defense requires Mr. Baker's knowledge to be contemporary to the patent application filing. Mr. Baker testifies in his supplemental declaration that he kept abreast

14. Dkt. # 259, Exhibit B, p. 71.

of developments in the field through consulting, teaching and various other activities from the time of his retirement through the time of the filing date of the '021 patent application.[15] Mr. Baker also explicitly qualifies his explanation of the level of skill in the art in terms of his knowledge of the field in 1997. Thus, the Court finds that Mr. Baker's knowledge of the field was not out-dated in 1997. Any objections that Neutrino maintains about Mr. Baker's specific consideration of issues relevant to the field in 1997 are appropriate material for cross-examination.

Neutrino also objects generally to the sufficiency of Mr. Baker's knowledge of the level of ordinary skill in the art in 1997. Neutrino's assertion that Mr. Baker "has no idea how to *legally* determine the level [of ordinary skill in the art] . . ." (emphasis added) misapprehends the proper inquiry into the level of ordinary skill in the art. The relevant analysis is factual. *Ryko Mfg.*, 950 F.2d at 718. Mr. Baker's factual conclusions about the level of ordinary skill in the art are under the purview of the jury so long as the Court determines that his testimony is reliable. Neutrino contends that the absence of analysis underlying Mr. Baker's factual conclusions about the level of ordinary skill fails the reliability analysis set forth under *Daubert*. However, Mr. Baker's conclusions about the level of ordinary skill in the art are nonscientific expert opinions based on specialized knowledge. *See* MCCORMICK ON EVIDENCE § 13. Where scientific knowledge is not at issue, the Court need not use the *Daubert* factors to determine reliability, but may gauge reliability from a more flexible analysis. *Kumho Tire*, 526

15. Sonosite's Exhibit 31.

U.S. at 149, 119 S.Ct. 1167. Mr. Baker's opinions as to the level of ordinary skill in the art are necessarily based on his own experience. In his supplemental declaration, Mr. Baker sets forth the education and experience necessary to be one of ordinary skill in the art and explains that he derived these standards from his own experience working and teaching in the field.[16] The Court is satisfied that Mr. Baker has ample experience in the field to reliably opine about the level of ordinary skill in the art.

Neutrino also argues that Mr. Baker's "real-world feasibility" testimony is not relevant because it "is not a correct focus in an enablement analysis."[17] The Federal Circuit Court of Appeals has articulated the test for enablement as follows:

> A decision on the issue of enablement requires determination of whether a person skilled in the pertinent art, using the knowledge available to such a person and the disclosure in the patent document, could make and use the invention without undue experimentation.

Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 941 (Fed.Cir.1990). Neutrino contends that testimony by Mr. Baker about the "feasibility" of designing the patented invention subjects the patent to a more rigorous analysis than that demanded by the "make and use . . . without undue experimentation" requirement of § 112. Specifically,

16. *Id.*

17. Dkt. # 258, p. 13.

Appendix E

Neutrino offers portions of Mr. Baker's deposition testimony that suggest Mr. Baker equated "feasibility" with commercial success.[18] The Federal Circuit has made clear that the requirements of § 112 do not require evidence that the patented device could be manufactured commercially. *See Christianson v. Colt Indus. Operating Corp.*, 822 F.2d 1544, 1562 (Fed.Cir.1987). Sonosite contends that Mr. Baker's opinions are relevant because they (1) "are expressed from the appropriate point of view (ordinary skill in the art)," and (2) "address the appropriate inquiry (undue experimentation)." Sonosite suggests that Mr. Baker's use of the term "feasibility" was essentially short hand for the factors the Federal Circuit has stated a court may consider in determining whether a disclosure would require undue experimentation.[19] It appears from Mr. Baker's report that he used the terms "feasibility" and "enablement" more or less interchangeably. In his deposition testimony, Mr. Baker concedes that he used the term "feasibility" to mean the

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18. *Id.* at 14.

19. Factors:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1371 (Fed.Cir.1999) (quoting *In re Wands*, 858 F.2d 731, 737 (Fed.Cir.1988)).

ability of one of ordinary skill in the art to make and use a "commercially acceptable product." In fact, Mr. Baker responded affirmatively to a deposition question about whether the prototype he considered would be "a final package ready for commercialization. . . ." "Title 35 does not require that a patent disclosure enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect." *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1338 (Fed.Cir.2003). Because Mr. Baker's analysis is based on a standard inapplicable to the proper inquiry under § 112, his testimony cannot assist the jury to resolve any fact relevant to Sonosite's enablement defense. The research and development model set forth in Mr. Baker's report simply answers the wrong question and, as such, is inadmissible under Federal Rule of Civil Procedure 402.

Thus, the Court finds that Mr. Baker may properly testify as to the ordinary level of skill in the art at the time of the '021 patent filing, but cannot testify as to enablement under § 112 based on the analysis contained in his report.

III. Don L. Berardinucci

Neutrino objects to the testimony of Dr. Berardinucci on the grounds that it is both irrelevant and unreliable. Neutrino's relevancy objection focuses on the contentions that Dr. Berardinucci's qualifications as a urologist are not relevant to his testimony about the utility of the patented device and his analysis focuses exclusively on one method contained in the '021 patent description that need not be

practicable for the '021 patent to be useful under 35 U.S.C. § 101.

Sonosite argues in response to Neutrino's relevancy objections that Dr. Berardinucci's testimony is not offered to establish a utility defense under § 101, but to suggest a lack of enablement under § 112. It appears that the confusion stems from Dr. Berardinucci's use of the term "operability" instead of "utility" or "enablement." However, Neutrino also contends that Dr. Berardinucci's opinions about whether "the device described and claimed in the '021 patent 'would cure erectile dysfunction by applying ultrasound energy to the penis in order to stimulate blood flow' "[20] are not relevant to *any* issue at bar. To support this contention, Neutrino advances a theory of patent construction that appears in various Neutrino pleadings dealing with the enablement defense. Essentially, Neutrino argues that the claims of the '021 patent do not describe a therapeutic device intended to stimulate blood flow in the penis in order to accelerate drug delivery to that region. Neutrino points out in other pleadings and deposition questioning that the claims of the '021 patent do not mention a penis or anything at all about erectile dysfunction, stimulating blood flow, or drug delivery.

The Court agrees that the claims of the '021 patent only expressly describe a device used to monitor various hemodynamic parameters. If § 112 only requires the '021 patent description to enable one of ordinary skill in the art to make and use this diagnostic device, then obviously

20. Dkt. # 260, p. 2 (citing Berardinucci Report, Exhibit A, p. 1).

testimony about whether the claimed device could achieve the therapeutic goals set forth in the description is irrelevant. The first paragraph of 35 U.S.C. § 112 states:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The enablement requirement of § 112 demands that the patent specification enable "those skilled in the art to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk A/S,* 108 F.3d 1361, 1365 (Fed.Cir.1997) (quoting *In re Wright,* 999 F.2d 1557, 1561 (Fed.Cir.1993)). The question the Court must resolve is what portions of the '021 patent compose the "claimed invention." Neutrino's enablement arguments rely on the "claimed invention" consisting of only the patent claims. Conversely, Sonosite's expert testimony on the issue of enablement indicates that Sonosite considers the therapeutic method outlined in the Summary of the Invention to be part of the "claimed invention."[21]

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21. Obviously, Section 112 expressly describes the "claimed invention" in terms of the written description in the specification. *See Markman v. Westview Instruments, Inc.,* 52 F.3d 967, 979 (Fed.Cir.1995). The Court does not interpret Neutrino's argument to

(Cont'd)

Appendix E

Because "the scope of the claims must be less than or equal to the scope of the enablement," *Nat'l Recovery Tech., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1196 (Fed.Cir.1999), it follows that the scope of the enablement may be broader than the claims. However, the written description need not enable anything broader than the scope of the claims. The fact that the claims dictate the minimum scope of enablement does not make all portions of the written description that do not literally and exactly reflect the terms of the claims irrelevant. To the contrary, enablement is determined based on the written description, and the features giving purpose to a claimed device in the written description are relevant to enablement even if absent in the literal terms of the claims. *See Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1196 (Fed.Cir.1999). For purposes of determining whether the enablement requirement of § 112 has been satisfied, the Court considers the claims interpreted in light of the specifications and drawings and the underlying purpose of the invention. The claims demarcate an area of invention within the exclusive possession of the patentee. The requirement that the patent

(Cont'd)

mean that the specification should be ignored all together, but that the parts of the specification that do not specifically interpret the terms of the claims are without the scope of the "claimed invention." For example, under Neutrino's interpretation, that portion of the specification describing the components of the diagnostic device would be within the scope of the "claimed invention," whereas any reference to a penis in the specification would not be within the scope of the "claimed invention" because a penis is not mentioned in the claims. Conversely, Sonosite seems to embrace a process of interpretation that would include the entire written description in the specification.

description be enabling is the quid pro quo the patentee must offer in exchange for exclusive possession. The written description in the patent must allow others in the field to realize this new technology and put it to use. Therefore, the claimed invention cannot be interpreted in the absence of the underlying purpose of the patent. *See Decca, Ltd. v. United States,* 210 Ct.Cl. 546, 544 F.2d 1070, 1077 (Ct.Cl.1976) ("The machine patented may be imperfect in its operation; but if it *embodies the general principle* and works . . . it is enough.") (emphasis added).

The 27 claims of the '021 patent only describe "an apparatus . . . to monitor hemodynamic parameters." However, the written description instructs that the "invention is directed toward a method and apparatus for stimulating and/or monitoring hemodynamic activity, such as blood flow, in a penis." The claims must be interpreted in light of this broader assertion. Because the described invention is for "stimulating *and/or* monitoring" (emphasis added), the claimed invention can monitor without the ability to stimulate.[22] Because the claims do not discuss stimulation, and because the specifications do not require the ability to both monitor *and* stimulate, the Court finds that the "claimed invention" is "directed toward a method and apparatus for monitoring hemodynamic activity. . . ." However, because the

22. The Court considered at length the possibility that the "and/or" designation might describe a device capable of both stimulating and monitoring, but with the ability to only do one or the other at a time. Although the descriptions support this interpretation, the explicit reference only to a monitoring capability in the claims leads the Court to conclude that only this use is part of the claimed invention.

general principle underlying the invention was expressly the treatment of erectile dysfunction, the Court finds that the "claimed invention," for purposes of the enablement analysis, is directed specifically and exclusively at the penis. Therefore, the Court finds that, in order for the '021 patent to satisfy the requirements of § 112, the patent description must enable one of ordinary skill in the art to make and use an apparatus capable of measuring hemodynamic activity in a penis.

The Court will analyze the relevance of Dr. Berardinucci's testimony in light of this interpretation of the "claimed invention" under the enablement defense. Neutrino contends that the analysis in Dr. Berardinucci's report is based entirely on the incorrect assumption that the '021 patent claims a therapeutic device. The Court agrees. Dr. Berardinucci states in his report that "I have been asked to review [the '021 patent], and form a professional, medical opinion as to whether the device described and claimed in that patent would cure erectile dysfunction by applying ultrasound energy to the penis in order to stimulate blood flow."[23] Because that analysis is not relevant to Sonosite's enablement defense, Dr. Berardinucci's opinions are irrelevant.[24]

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23. Dkt. # 260, Exhibit A, p. 1.

24. The Court notes that, even if the claimed invention did include the therapeutic method contained in the description, Dr. Berardinucci's testimony would be irrelevant because he states that he does not express any opinion about whether or not ultrasound energy transmitted into the penis would stimulate blood flow. (Cont'd)

Appendix E

IV. Cameron Weiffenbach

Neutrino objects to the testimony of Cameron Weiffenbach on the issues of "new matter" and "inequitable conduct" on the grounds that both are irrelevant and unreliable. Specifically, Neutrino objects to the relevancy of Mr. Weiffenbach's critique of the Patent Office practices and procedures and his testimony about Richard Redano's status as a registered patent attorney. Neutrino also argues that Mr. Weiffenbach's testimony about "new matter" and "inequitable conduct" are not supported by any of the *Daubert* reliability factors. Finally, Neutrino contends that certain portions of Mr. Weiffenbach's testimony are impermissible instructions on the law to the jury.

Neutrino concedes that Mr. Weiffenbach's general testimony regarding the patenting process and Patent Office ("PTO") procedures are appropriate expert testimony that he is qualified to offer. However, Neutrino objects to testimony suggesting deficiencies in the PTO process that might serve to undermine the presumption of validity afforded final determinations of the PTO.[25] Sonosite argues that Mr. Weiffenbach's testimony that the patent examiner

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(Cont'd)

Dr. Berardinucci's testimony is only that ultrasound energy could not cause an erection. The '021 patent never suggests that ultrasound energy could cause an erection. The therapeutic method in the description suggests that ultrasound energy could stimulate blood flow in the penis and thereby accelerate the delivery of drugs designed to cure erectile dysfunction.

25. The presumption of validity is codified at 35 U.S.C. § 282.

committed several errors during prosecution of the '021 patent is relevant to the issue of whether or not Richard Redano deliberately took advantage of an error by the PTO to include a "new matter" in the '021 patent. Sonosite contends that Mr. Weiffenbach's testimony establishes that the PTO made errors and that Redano would have recognized those errors and therefore the amendment made to the '021 patent was procured through inequitable conduct. Neutrino argues, however, that evidence of problems in the PTO prosecution is not admissible. To support this contention, Neutrino cites to a case where a district court refused to allow an expert "to speculate about possible defects, errors, or omissions in the application process." that would serve to undermine the presumption of validity afforded final determinations by the PTO. *Bausch & Lomb, Inc. v. Alcon Labs., Inc.*, 79 F.Supp.2d 252, 255-56 (W.D.N.Y.2000).

The Court finds that, to the extent that Mr. Weiffenbach's testimony simply addresses the potential pressures and potential for error at the PTO, such testimony is inadmissible. *See American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360 (Fed.Cir.1984). Such general testimony tends to undermine the presumption of validity. However, the fact that invalidity defenses are permitted indicates that the presumption of validity is a rebuttable presumption. Evidence of mistakes or misconduct during the patent prosecution are relevant to determining the actual validity (as opposed to the presumed validity) of the patent. "[T]he examiner's and the applicant's absolute compliance with the internal rules of the patent examination" is relevant where there is evidence of inequitable conduct. *Magnivision, Inc. v. Bonneau Co.*, 115 F.3d 956, 960-61 (Fed.Cir.1997).

Therefore, the Court finds that testimony about specific PTO errors in the prosecution of the '021 patent are admissible to show inequitable conduct.

For similar reasons, the Court finds that testimony that Richard Redano was a registered patent attorney at the time of the patent prosecution is proper. Sonosite contends that "registered patent attorneys are presumed to know the patent law and PTO rules and procedures."[26] The Court agrees that the jury could reasonably find that Richard Redano's trained knowledge of patent law suggests that he would have been aware of certain PTO errors and consequently, that he took advantage of those errors and expanded the scope of the '021 patent through fraud.

Neutrino also objects to Mr. Weiffenbach's opinion that Richard Redano's legal conclusion that "no new matter has been added" in the May 4th amendment and the November 14th amendment was a misrepresentation to the PTO on the grounds that "Mr. Redano's legal arguments to the Patent Office cannot, as a matter of law, constitute inequitable conduct."[27] Neutrino contends that "statements of fact or legal arguments made by the prosecuting party" are immaterial to the issue of a patent's validity.[28] Sonosite argues that this is not true in the context of an inequitable conduct defense. The Court agrees. Neutrino's characterization of the

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26. Dkt. # 301, p. 28.

27. Dkt. # 261, p. 20.

28. *Id.* at 21.

presumption of validity suggests that the law presumes that the patent examiner did not rely on misrepresentations made by the applicant. To the contrary, if the misrepresentations made were material, the law presumes that the entire application was tainted by deceit. *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed.Cir.1995); *see also* 37 C.F.R. § 1.56 (2003). Therefore, material representations made by Richard Redano to the PTO during the prosecution are relevant to the issue of inequitable conduct. That clarified, the Court finds, however, that Mr. Weiffenbach's opinions about the misrepresentative nature of Mr. Redano's statements to the PTO are based on opinions he is unqualified to offer. As set forth in the following paragraphs the Court finds that Mr. Weiffenbach is unqualified to testify about whether the amendments made to the '021 patent were in fact "new matter."

Neutrino contends that Mr. Weiffenbach is not qualified to testify about whether or not material contained in the May 4th and November 14th amendments was "new matter" on the grounds that he is not "one of ordinary skill in the art." Neutrino claims that the relevant inquiry is whether one of ordinary skill in the art would have understood that the material contained in the amendments was "new matter." The Court has already resolved the art area as "the designing, testing, and building" of medical ultrasound devices. Sonosite does not argue that Mr. Weiffenbach is skilled in this area, but instead contends that he is particularly qualified to consider the patent application materials from the perspective of a patent examiner and patent attorney and his testimony serves to tie the technical opinions of Dr. Jens Quistgaard and Ms. Joan Baker on the issue of "new matter" to the

prosecution record of the '021 patent. For an amendment to a patent application to comply with 35 U.S.C. § 132, *a person of ordinary skill in the art* must be able to look at the patent application as of the filing date and determine that the claimed invention included the later-claimed subject matter. *TurboCare Div. of Demag Delaval Turbomach. Corp. v. Gen. Elec. Co.*, 264 F.3d 1111, 1118-19 (Fed.Cir.2001). The law makes no exception for the expert testimony of patent examiners, patent attorneys, or any other patent law experts. If the witness is unqualified to testify from the perspective of "one of ordinary skill in the art," then his testimony is inadmissible on the issue of "new matter." Therefore, the Court agrees with Neutrino that Mr. Weiffenbach is not qualified to testify as to whether the amendments constituted "new matter" as prohibited by the written description requirement of § 112.

The Court's finding that Mr. Weiffenbach is not qualified to testify as to whether amendments made to the '021 patent constituted "new matter" seriously limits the scope of his testimony about errors made during the patent prosecution. Mr. Weiffenbach can properly testify as to any actual defects that occurred in the application process, but he is not qualified to identify any amendment made to the '021 patent as "new matter" and, therefore, cannot properly conclude that the patent examiner committed an error by failing to identify such as "new matter." Mr. Weiffenbach's testimony should be strictly limited to a general examination of the patent application process and any specific irregularities in prosecution of the '021 patent that he is qualified to identify. *See Bausch & Lomb, Inc. v. Alcon Laboratories, Inc.*, 79 F.Supp.2d 252, 255-56 (W.D.N.Y.2000) (only allowing

expert witness who was a former patent examiner to testify about general patent application process and any "evidence that there actually were defects in the particular application process at issue."); *see also Applied Materials, Inc. v. Advanced Semiconductors Materials America, Inc.*, 1995 WL 261407, *3 (N.D.Cal. Apr.25, 1995). Similarly, Mr. Weiffenbach's testimony about misrepresentations made by Richard Redano should be limited to defects in the particular application process that a patent attorney would have recognized, and should not convey any opinion about whether or not Redano would have recognized the amendments made to the '021 patent as "new matter." However, other opinions about Redano's knowledge, such as knowledge that "he was supposed to particularly point out support in the original filed '021 Patent application for his statement that 'no new matter has been added' "[29] are appropriate.

Neutrino also objects to certain portions of Mr. Weiffenbach's testimony as improper instructions on the law to the jury. Specifically, Neutrino contends that Mr. Weiffenbach's opinion that Redano did not conceive of the claimed device and Mr. Weiffenbach's opinion regarding the explicit or inherent disclosures of the '901 patent are impermissible instructions to the finder of fact. Certainly, Neutrino is correct to point out that witness testimony regarding what the law requires is unnecessary and improper. *See Owen v. Kerr-McGee Corp.*, 698 F.2d 236, 239-40 (5th Cir.1983). Sonosite argues that Mr. Weiffenbach's testimony is not designed to instruct the jury on the law because it is

29. Dkt. # 310, p. 37.

"couched in terms of the evidence that the expert considered."[30] However, the Court finds that portions of Sections B and C on pages 60 and 61 of Mr. Weiffenbach's report attempt to explain the legal standards as opposed to offering appropriate conclusions in terms of legal standards. Therefore, that portion of Mr. Weiffenbach's testimony regarding the concept of priority that explains how a claim is entitled to a particular filing date is an unnecessary explanation of the law that should be excluded. Furthermore, Mr. Weiffenbach is not qualified to testify about the claimed device under the '901 patent. As discussed above, Mr. Weiffenbach is not one of ordinary skill in the art and therefore his testimony about facts necessary to establish the understanding of one of ordinary skill in the art is not helpful to the trier of fact.

Similarly, that portion of Mr. Weiffenbach's testimony regarding inventorship that explains the legal standard for inventorship and conception is not an appropriate subject for expert testimony. Furthermore, the Court finds that the subsequent testimony regarding the disclosures made in the '021 patent are inadmissible as Mr. Weiffenbach is unqualified to opine about what one of ordinary skill in the art would understand from the written description and claims of the '021 patent. Contrary to Sonosite's assertion, "specialized knowledge and experience in the patent field" does not automatically qualify Mr. Weiffenbach to testify about every aspect of the '021 patent.

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30. Dkt. # 301, p. 43 (citing *Fiataruolo v. United States*, 8 F.3d 930, 942 (2d Cir.1993)).

Finally, Neutrino objects to Mr. Weiffenbach's testimony regarding the disclosure of the Pohl Patent (U.S. Patent No. 5,578,060) on the grounds that he is not qualified to testify as one of ordinary skill in the art. Contrary to Sonosite's argument that "Mr. Weiffenbach's 30 years of experience as a patent practitioner and former patent examiner qualify him to offer this testimony," the law demands that testimony on the disclosures of a patent be offered from the perspective of one of ordinary skill in the art. *See Adang v. Fischhoff,* 286 F.3d 1346, 1355 (Fed.Cir.2002); *In re Wands,* 858 F.2d 731, 737 (Fed.Cir.1988). Mr. Weiffenbach's experience in the field of patent lawyering is simply irrelevant and his testimony about the Pohl Patent is inadmissible.

V. Jens U. Quistgaard

Neutrino seeks to exclude the testimony of Jens Quistgaard ("Dr.Quistgaard") in two motions. The first motion claims that there is no reliable basis for Dr. Quistgaard's opinions on "new matter," "enablement," and "anticipation," and further that opinions regarding examiner error are impermissible. The second motion contends that Dr. Quistgaard's "lack of infringement" opinions are unreliable and should be excluded.

First, Neutrino asserts that Dr. Quistgaard's "new matter" testimony is unreliable because it is not offered from the perspective of one of ordinary skill in the art. Neutrino contends that Dr. Quistgaard "has not established that he possesses any specific knowledge of who 'one of ordinary skill in the art' is, or what this individual would have concluded from reading the patent application at the time of

its filing."[31] Sonosite argues that Dr. Quistgaard did qualify the conclusions of his report in terms of "one of ordinary skill in the art" and that Neutrino failed to question him about what he believes the level of ordinary skill in the art to be and whether he applied that standard to his opinions. The Court believes that the following introductory passage from Dr. Quistgaard's report resolves the issue of the application of the "one of ordinary skill in the art" standard:

As a result of my education and experience, I am very familiar with medical ultrasound technology, and designing, testing and building medical ultrasound devices, including analyzing their structure and how they function and perform. I believe that I am an expert in this field and can provide opinions on how one with ordinary skill in this art would understand the structure, function and performance of devices described in patent disclosures such as ones in U.S. patents 5,947,901 and 6,221,021.[32]

The Court is satisfied that Dr. Quistgaard's qualifications support this opinion. Any exception Neutrino takes to Dr. Quistgaard's formulation or application of the level of ordinary skill in the art is a factual dispute ripe for cross-examination.

Neutrino also objects to Dr. Quistgaard's "enablement" opinions on the grounds that he failed to conduct analysis from the perspective of one of ordinary skill in the art and

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31. Dkt. # 262, p. 3.

32. Dkt. # 262, Exhibit A, Quistgaard Report, p. 24.

he failed to focus on the invention claimed in the '021 patent. As discussed above, the Court is satisfied that Dr. Quistgaard has conducted his analysis from a legally acceptable formulation of the level of ordinary skill in the art. If Neutrino disagrees with the facts underlying Dr. Quistgaard's formulation and application of that standard, it is free to explore the basis for its disagreement on cross-examination. Neutrino's contention that Dr. Quistgaard failed to focus on the "claimed invention" when analyzing the '021 patent under § 112 is based on the same excessively narrow interpretation of the "claimed invention" discussed above in relation to the testimony of Dr. Berardinucci. Neutrino objects to Dr. Quistgaard's reliance on the proportions of the device depicted in the drawings on the grounds that the Court's claim construction simply described the ultrasonography generator as "[a] body that is sized such that it can be held by hand and, so held, moved from one location to another." However, as the Court discussed above, construction of the claims to determine the scope of possession for purposes of identifying infringement is different than analysis of the claimed invention for purposes of determining enablement under § 112. The enablement analysis asks whether the written description, including the drawings, allows enablement at least as broad as the scope of the claims. If Neutrino contends that the written description in the '021 patent would enable one of ordinary skill in the art to make and use a device with capabilities at least as broad as the claims, it is appropriate for Sonosite's enablement expert to look to the written description, including the drawings to see if they so instruct. Neutrino's objection to this testimony is misplaced.

Appendix E

Neutrino also objects to Dr. Quistgaard's opinions regarding patent examiner error on the ground that such testimony is an inappropriate attempt to rebut the presumption of validity afforded a duly granted patent. Sonosite argues in response that Dr. Quistgaard's opinion is not generalized testimony about problems in the PTO, but identifies specific defects in the prosecution of the '021 patent that undermine its validity. As discussed above, the presumption of validity is a rebuttable presumption and therefore does not preclude all evidence of patent prosecution defects. The prohibition against generalized testimony about problems in the PTO articulated in cases such as *Bausch & Lomb, Inc. v. Alcon Labs., Inc.*, 79 F.Supp.2d 252, 255-56 (W.D.N.Y.2000), and *Applied Materials, Inc. v. Adv. Semiconductor Materials America, Inc.*, 1995 WL 261407, *3 (N.D.Cal.1995), is designed to prevent the burden of proof from being shifted to the party defending a patent's validity upon a showing of irregularities in the patent prosecution. Even evidence of specific prosecution defects, such as that offered in Dr. Quistgaard's testimony, cannot shift the burden of proof from the defendant. However, this does not make specific evidence of prosecution defects irrelevant. As the Court explained above, evidence of specific prosecution defects can be relevant to the issue of inequitable conduct. Dr. Quistgaard offers his opinion that two erroneous statements were made by the patent examiner in connection with his investigation into "new matter." Dr. Quistgaard's testimony is essentially that Richard Redano made incorrect statements about the hand-held nature of the ultrasonography generator to the patent examiner and that the patent examiner erroneously found support for the hand-held amendment in a patent incorporated by reference in the original patent

application.[33] Testimony about the patent examiner's allegedly erroneous interpretation of United States Patent No. 5,983,783 is relevant to the issue of "new matter" and, therefore, admissible.

Finally, Neutrino contends that there is no reliable basis for Dr. Quistgaard's opinion that the Diasonics ultrasound device anticipates the claims of the '021 patent on the grounds that Dr. Quistgaard offers no facts to support this conclusion in his report. Typically, testimony concerning anticipation must identify each claim element, state the witnesses' interpretation of the claim element and explain in detail how each claim element is disclosed in the prior art reference. *Schumer v. Laboratory Computer Sys., Inc.*, 308 F.3d 1304, 1315-16 (Fed.Cir.2002). Testimony is insufficient if it is merely conclusory. *Id.* Dr. Quistgaard states in his deposition testimony that he based his conclusion on a comparison of the claims of the two devices, but fails to explain how each claim of the '021 patent is disclosed in the claims of the Diasonics patent. As such, Dr. Quistgaard's testimony on the issue of anticipation of the Diasonics device is not sufficiently reliable under *Daubert* and is therefore inadmissible.

In its second motion pertaining to the testimony of Dr. Quistgaard, Neutrino contends that his opinions on "lack of infringement" are unreliable on the grounds that (1) the Court has already determined that Sonosite's "old products" literally infringe the '021 patent, (2) Dr. Quistgaard's reverse doctrine of equivalents analysis is flawed as a matter of law, (3) Dr. Quistgaard failed to apply the Court's *Markman* claim

33. Dkt. # 262, Exhibit A, pp. 3-4.

construction, and (4) Quistgaard incorrectly applies an invalidity defense to his infringement analysis.

Neutrino contends that Dr. Quistgaard's opinion that "none of Sonosite's medical ultrasound products infringe any of the claims"[34] of the '021 patent is inappropriate because the Court already found that certain Sonosite products literally infringe the '021 patent.[35] Sonosite argues in response that the Court's rulings did not apply to 5 of the 9 Sonosite products that Neutrino alleges infringe the '021 patent. Both Parties are correct. Dr. Quistgaard's testimony that the Sonosite 180, the Sonosite 180 PLUS, the SonoHeart, and the SonoHeart PLUS do not literally infringe the '021 patent or are so far changed from the claimed invention in the '021 patent as to not infringe under the reverse doctrine of equivalents is irrelevant because the Court has already held otherwise. That is, the Court has already determined that these products do literally infringe the '021 patent and the reverse doctrine of equivalents does not apply. However, the Court's previous Order does not address the SonoHeart Elite, the iLook 15, the iLook 25, the TITAN, and the MicroMaxx. As the Court has not resolved the issue of infringement with regard to these five newer devices, Dr. Quistgaard's testimony on the matter is still relevant. However, to the extent that any of Dr. Quistgaard's testimony relies on an interpretation of the '021 patent claims and written description that does not include an ultrasonography generator contained within a body sized to be hand-held, such

34. Dkt. # 266, p. 2.

35. Dkt. # 162.

testimony is irrelevant. The Court has held, and has reemphasized several times, that the claims of the patent include an ultrasonography generator within a "body that is sized such that it can be held by hand . . . ." The Court has found that the claims of the patent include such a description of the ultrasonography generator for purposes of determining literal infringement and that the written description includes the ultrasonography generator within a hand-held body for purposes of determining enablement under § 112 and for evaluating infringement under the reverse doctrine of equivalents.[36]

Sonosite contends that the written description and the claims were improperly amended to include the "sized to be hand-held" language and that, therefore, the patent should not be read to include a hand-held ultrasonography generator for purposes of determining infringement and applying the reverse doctrine of equivalents. Sonosite's argument confuses the distinct analyses applied to a determination of infringement and a determination of invalidity. If Richard Redano amended the '021 patent to include matter that was not supported in the original patent application, then that "new matter" invalidates the entire patent. If the patent is

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36. U.S. Pat. No. 6,221,021, preferred embodiment:

> . . . the display is located or mounted in a portable unit, such as the ultrasonography generator. As shown in Fig. 2, the ultrasonography generator unit is sized to be grasped or held in a user's hand. In the preferred embodiment shown in Fig. 3, the system is physically housed or located within the ultrasonography generator unit.

invalid, obviously Sonosite's devices cannot infringe it. However, the Court's infringement analysis is applied presuming the validity of the patent. The Court did not evaluate whether the amendments made to the '021 patent in May and November of 2000 were "new matter" when determining that the Sonosite devices then at bar literally infringed the '021 patent. Nor did the Court evaluate the amendments for "new matter" when deciding that Sonosite had failed to produce evidence that the reverse doctrine of equivalents should apply. Dr. Quistgaard is certainly qualified to testify about "new matter," as the Court found above, but, to the extent that Dr. Quistgaard's opinions about infringement assume that "new matter" was improperly added to the '021 patent, those opinions are irrelevant. If the Court or the jury finds that "new matter" was improperly added to the '021 patent, then the Court's finding of literal infringement is irrelevant because the '021 patent is invalid. But, the finding of infringement and the application of the reverse doctrine of equivalents is based strictly on the formulation of the '021 patent the PTO accepted and is presented to this Court as U.S. Pat. No. 6,221,021. With that limitation articulated, the Court declines to determine at this time whether or not the finding of literal infringement as to the Sonosite 180, the Sonosite 180 PLUS, the SonoHeart, and the SonoHeart PLUS applies to the SonoHeart Elite, the iLook 15, the iLook 25, the TITAN, and the MicroMaxx.

VI. Lauren S. Pflugrath

Neutrino challenges the reliability of Lauren S. Pflugrath's "anticipation" and "obviousness" opinions on the grounds that he failed to consider and properly apply the

perspective of "one of ordinary skill in the art." Neutrino also objects to Mr. Pflugrath's "obviousness" opinions on the grounds that he failed to consider any of the *Graham* factors in his analysis.

Neutrino contends that Mr. Pflugrath failed to make any investigation into the appropriate level of ordinary skill in the art and that, consequently, his opinions on "anticipation" and "obviousness" are unreliable. Neutrino contends that the absence of factual analysis underlying Mr. Pflugrath's conclusions applying the level of ordinary skill fails the reliability analysis set forth under *Daubert*. However, Mr. Pflugrath's conclusions about the level of ordinary skill in the art are nonscientific expert opinions based on specialized knowledge. *See* McCormick on Evidence § 13. Where scientific knowledge is not at issue, the Court need not use the *Daubert* factors to determine reliability, but may gauge reliability from a more flexible analysis. *See Kumho Tire*, 526 U.S. at 149, 119 S.Ct. 1167. Mr. Pflugrath's opinions as to the level of ordinary skill in the art are necessarily based on his own experience. Mr. Pflugrath qualified his opinions on "obviousness" and "anticipation" by stating that the '021 patent's defects would be evident to one of ordinary skill in the art. Furthermore, when questioned about the level of skill applied, Mr. Pflugrath began to explain the knowledge that one of ordinary skill in the art would possess, but was interrupted by Neutrino's counsel.[37] Mr. Pflugrath explained in his errata sheet to that deposition that he developed his understanding of the level of ordinary skill in the art from his experience designing, testing, and building medical ultrasound devices. The Court is satisfied that Mr. Pflugrath understood and employed the "one of

ordinary skill in the art" standard to his opinions on "anticipation" and "obviousness." The appropriate level of ordinary skill in the art of designing, testing, and building medical ultrasound devices is a factual determination to be resolved by the jury. Neutrino correctly points out that, if Mr. Pflugrath testified based on his own perspective and that he possesses "extraordinary," not ordinary, skill in the art, then his conclusions are improper. *See Custom Accessories v. Jeffrey-Allan,* 807 F.2d 955, 962 (Fed.Cir.1986); *Environmental Designs, Ltd. v. Union Oil Co. of California,* 713 F.2d 693 (Fed.Cir.1983) (holding that "one of ordinary skill in the art" is not a judge, layman, those skilled in remote arts, or "the geniuses in the art."). However, Mr. Pflugrath never asserts that he applied his own perspective to his "anticipation" and "obviousness" analysis. Expert witnesses quite often have *extraordinary* skill in the art and are perfectly capable of evaluating the level of *ordinary* skill and applying that perspective. The witness himself need not be the hypothetical ordinary artisan. The hypothetical person of ordinary skill in the art is a legal construct. Neutrino is free to challenge Mr. Pflugrath's formulation of the level of ordinary skill in the art on cross-examination.

Neutrino also contends that Mr. Pflugrath's "obviousness" opinions are unreliable because he failed to analyze any of the secondary considerations (i.e. *Graham* factors) that he articulated in his Report. "Under section 103, a patent may not be obtained if the differences between the claimed invention and the prior art are such that the invention as a whole would have been obvious at the time the invention

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37. Dkt. # 267, Exhibit C, pp. 79-80.

was made to a person having ordinary skill in the art to which the invention pertains." 1 Patent Law, Legal and Economic Principles § 1.30 (2d ed.). Four facts must be determined to establish the "obviousness" of a patented device. First, what is shown or disclosed by the pertinent prior art must be determined. Second, the differences between the claimed invention and the prior art must be identified. Third, there must be an assessment as to the level of ordinary skill in the art to which the invention related at the time the invention was made. Finally, the circumstances that surround the historical origins of the claimed invention and its effect on the industry must be considered. *See Graham v. John Deere Co.*, 383 U.S. 1, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966). Neutrino argues that Mr. Pflugrath's "obviousness" opinions are unreliable because he failed to consider the fourth step of this factual analysis. Specifically, Neutrino contends that Mr. Pflugrath failed to consider the commercial success of the infringing Sonosite devices. The Supreme Court has held that evidence of commercial success may be a relevant indication of nonobviousness. *Graham*, 383 U.S. at 17-18, 86 S.Ct. 684. Sonosite argues in response that "Mr. Pflugrath explicitly recognized in his report that 'when making a determination of obviousness various factors must be considered so as to avoid the use of hindsight, such as whether the invention . . . was commercially successful . . . .' "[38] The Court agrees that Mr. Pflugrath's statement indicates that he was aware of the relevance of the *Graham* factors to the obviousness analysis. Mr. Pflugrath's opinions are not unreliable simply because he did not concede Neutrino's contention that the commercial success of Sonosite's devices

38. Dkt. # 291, p. 6 (quoting Dkt. # 267, Exhibit A, pp. 3-4).

indicates that the claimed invention in the '021 patent was nonobvious. Mr. Pflugrath's testimony presents facts relevant to the obviousness analysis. Factual evidence that tends to contradict Mr. Pflugrath's conclusions is appropriate material for cross-examination.

VII. Stephen M. Graham

Neutrino objects to the testimony of Stephen Graham on the grounds that Sonosite failed to timely designate him as an expert witness. Sonosite contends that Mr. Graham will only testify as a fact witness about legal actions with which he was involved as Sonosite's corporate counsel. Neutrino concedes that Mr. Graham was disclosed as a fact witness, but contends that his testimony on the legal effect of certain Securities and Exchange Commission ("SEC") filings cannot qualify as "lay testimony" under Federal Rule of Evidence 701. Sonosite argues that "Mr. Graham's testimony concerning [SEC filings] will consist exclusively of recounting, as a matter of historical fact, what Sonosite did, and why."[39] The Court agrees that this is proper testimony from a fact witness. Neutrino has had sufficient notice of Mr. Graham's role as corporate counsel to Sonosite and his specific involvement with the SEC filings at issue. Therefore, the Court finds that Mr. Graham may properly testify as a fact witness about matters with which he was personally involved, including advice he gave, as Sonosite's corporate counsel.

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39. Dkt. # 349, p. 5.

Appendix E

CONCLUSION

For the foregoing reasons, the Court finds that Plaintiff's motions to exclude (Dkt. # s 258, 267, and 343) should be DENIED, Plaintiff's motion to exclude (Dkt.# 260) should be GRANTED, and Plaintiff's motions to exclude (Dkt. # s 259, 261, 262, and 266) should be GRANTED in part and DENIED in part.

It is so ORDERED.

APPENDIX F — MEMORANDUM AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF TEXAS, HOUSTON DIVISION FILED MARCH 30, 2007

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

CIVIL ACTION NO. H-01-2484

NEUTRINO DEVELOPMENT CORPORATION,

Plaintiff,

v.

SONOSITE, INC.,

Defendant.

MEMORANDUM AND ORDER

Pending before the Court is Defendant's Motion for Exceptional Case and Attorneys' Fees (Dkt. #368). The Court, after reviewing the motion, the responses of the parties and the relevant law, is of the opinion that the motion should be DENIED.

Factual and Procedural Background

In May of 1999, Richard Redano ("Redano") filed a patent application ("the '021 patent application") with the Patent and Trademark Office ("PTO") disclosing a "method

and apparatus for penile hemodynamic stimulation, monitoring, and drug delivery acceleration."[1] The original application contained 20 claims. In November 1999, Redano wrote a letter to Dr. Juin-Jet Hwang, Chief Technology Officer of Sonosite Inc. ("Sonosite"), offering to disclose the claims of the '021 patent application upon execution of a nondisclosure agreement, summarizing the purpose of the invention to be patented, and inquiring as to whether Sonosite would be interested in licensing the '021 patent once issued.[2] Redano received an email response from Dr. Hwang indicating that Sonosite was not interested in therapeutic ultrasound technology. In response, Redano sent a facsimile to Dr. Hwang cautioning that "[o]nly time will tell the degree to which the pending applications will cover imaging technology."[3]

On February 4, 2000, the PTO rejected all 20 claims of the '021 patent application on various grounds.[4] On May 4, 2000, Redano filed an "Amendment and Response to First Action" in which he added new claims 21-37.[5] In new claim 30, the language "sized to be hand held" appeared for the first time with regard to the ultrasonography generator component of the invention. On July 19, 2000, the PTO

1. Defendant's Motion, Exhibit 5, CW 1742.

2. Defendant's Motion, Exhibit 11, P 2877.

3. *Id.* at P 2885.

4. Defendant's Motion, Exhibit 5, CW 1777.

5. *Id.* at CW 1786.

notified Redano that he had to elect between prosecution of claims 1-2, 8-9, 11-12, 14-16, 18, and 21 (pertaining to the therapeutic device and methods) or claims 22-37 (pertaining to the diagnostic device).[6] On July 27, 2000, by way of telephone interview, Redano elected to prosecute claims 22-37 without traverse.

On July 31, 2000, the PTO rejected claims 22-37 "under the doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 5931783." This action, however, was overcome in November 2000 when Redano filed a terminal disclaimer with regard to the '783 patent (also held by Redano). At that time, Redano also amended the claims of the '021 patent application by cancelling claims 29 and 37, and adding new claims 38-50. On April 24, 2001, the '021 patent issued with 27 claims taken from portions of application claims 22-50.

On July 24, 2001, Neutrino Development Corp. ("Neutrino"), which had licensed the '021 patent from Redano, filed the present infringement action against Sonosite. On August 29, 2001, Neutrino filed a motion for a preliminary injunction (Dkt. #8), which the Court denied by Order of October 4, 2001 (Dkt. #30). On February 20, 2002, after extensive briefing, the Court held a one-day *Markman* hearing and subsequently issued an Order on August 20, 2003 construing certain claims of the '021 patent (Dkt. #125). Based on that claim construction, the Court later found that four devices manufactured and marketed by Sonosite (the Sonosite 180, SonoHeart, 180 PLUS, and the SonoHeart

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6. *Id.* at CW 1799.

PLUS) literally infringed the '021 patent (Dkt. #162). However, after considering the prosecution of the '021 patent in greater detail, the Court found that Redano had improperly added "new matter" when the '021 patent application was amended in May of 2000. Consequently, the Court found that certain claims of the '021 patent at the center of this lawsuit are invalid for new matter and entered a final judgment in favor of Sonosite (Dkt. #363 and Dkt. #364).

Sonosite has filed the present post-judgment motion requesting that the Court find that this is an "exceptional case" under 35 U.S.C. § 285 and award attorneys fees and certain non-taxable costs to Sonosite as the prevailing party.

Analysis

35 U.S.C. § 285 allows a court to award attorneys fees to a prevailing party in an "exceptional case."[7] An award of attorney fees under § 285 involves a two-part determination. First, a district court must determine whether the prevailing party has proven an exceptional case by clear and convincing evidence. *Forest Labs., Inc. v. Abbott Labs.*, 339 F.3d 1324, 1327 (Fed. Cir. 2003) (citing *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 669 (Fed. Cir. 2000)). Second, if the district court finds that the case is exceptional, it must then determine whether an award of attorney fees is appropriate. *Id.* An award of attorneys fees is appropriate "where it would be *grossly unjust* that the winner be felt to bear the burden of his own

7. 35 U.S.C. § 285:

> The court in exceptional cases may award reasonable attorneys fees to the prevailing party.

counsel." *J.P. Stevens Co. v. Lex Tex Ltd., Inc.*, 822 F.2d 1047, 1052 (Fed. Cir. 1987) (emphasis in original).

The "clear and convincing" standard of proof is an intermediate standard which lies somewhere between "beyond a reasonable doubt" and a "preponderance of the evidence." *Addington v. Texas*, 441 U.S. 418, 425 (1979). Although not susceptible to precise definition, "clear and convincing evidence" has been described as evidence which produces in the mind of the trier of fact "an abiding conviction that [the] truth of the factual contentions are 'highly probable.'" *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984); *see also Shafer v. Army & Air Force Exchange Srvc.*, 376 F.3d 396 (5th Cir. 2004) (instructing that clear and convincing evidence is "that weight of proof which 'produces in the mind of the trier of fact a firm belief or conviction as to the truth of the allegations sought to be established, evidence so clear, direct and weighty and convincing as to enable the fact finder to come to a clear conviction, without hesitancy, of the truth of precise facts' of the case." (quoting *In re Medrano*, 956 F.2d 101, 102 (5th Cir. 1992))). For purposes of the motion at bar, Sonosite bears the burden of presenting clear and convincing evidence that Neutrino's conduct makes this an "exceptional case."

"Types of conduct that might support a showing of exceptional circumstances include willful infringement, inequitable conduct before the Patent and Trademark Office, litigation misconduct, and vexatious or unjustified litigation or frivolous suit." 69 C.J.S. PATENTS § 532; *see also Evident Corp. v. Church & Dwight Co., Inc.*, 399 F.3d 1310, 1315 (Fed. Cir. 2005) (finding that "[e]xceptional cases are

normally those involving bad faith litigation or those involving inequitable conduct by the patentee in procuring the patent"). Sonosite alleges that "Redano is guilty of inequitable conduct because of his actions in prosecuting the '021 Patent, and his litigation misconduct— directly and through the actions of his attorneys and agents— for vexatious litigation tactics associated with the filing and aggressive pursuit of this litigation on a patent that he knew he had obtained illegally."[8] The Court will address the allegations pertaining to the period of patent prosecution and the present litigation separately.[9]

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8. Defendant's Motion, p. 2.

9. In its response to Sonosite's motion, Neutrino argues that the doctrine of *Res Judicata* and/or the Plaintiff's jury demand bars the Court from making post-judgment findings of fact to make a determination of "exceptional case." This antic contention is completely without foundation. The Federal Rules of Civil Procedure specifically provide that the district court shall make findings of fact and conclusions of law when awarding attorneys fees post-judgment. *See* FED. R. CIV. P. 54(d)(2). There are many instances in which the court makes findings of fact when disposing of certain post-judgment claims. An apt example would be the disposition of a motion for relief from judgment under Federal Rule 60(b)(3) based on the fraud of a party. In such a case, the court would make factual findings to determine whether fraud was committed. Similarly, in a motion for post-judgment relief based on an allegation of inequitable conduct, the court is the finder of fact and arbiter of law. In making such post-judgment factual findings, the court can go so far as to permit the parties to conduct limited discovery on the issues. Therefore, there is no basis for the Court to entertain Neutrino's request for a trial on the issue of inequitable conduct. Furthermore, *Res Judicata* is inapplicable to a single action. In the event that

(Cont'd)

Appendix F

A. Inequitable Conduct During the Prosecution of the '021 Patent

Sonosite contends that Redano "commit[ted] fraud on the U.S. Patent & Trademark Office ("PTO") by broadening his patent application" to cover an ultrasonography generator that is sized to be hand-held.[10] More specifically, Sonosite argues that Redano intentionally added new matter to the amendments of the '021 patent application with knowledge that such new matter would invalidate the patent. Sonosite further alleges that Redano intentionally misled the patent examiner by falsely representing that there was "no new matter" in the amendments to the '021 patent. In response, Neutrino argues that Redano withheld nothing from the patent examiner and he thereby complied "with all the rules and regulations and discharge of his duty of candor."[11] Neutrino further argues that "Mr. Redano's state of mind has been, at all times prior to the filing of the amendment in question, through the present, to fully comply with PTO rules and to fully, completely and promptly discharge his duty of candor."[12]

(Cont'd)
Neutrino has confused the doctrines of claim and issue preclusion, the Court notes that the related doctrine of issue preclusion is inapplicable where, as here, the issue at bar has never been adjudicated. An order of final judgment does not limit the Court's ability to make factual findings on a motion for attorneys fees.

10. Plaintiff's Motion, p.2.

11. Plaintiff's Surreply, p. 9.

12. *Id.* at 11.

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In order "[t]o prove inequitable conduct in the prosecution of a patent, [the defendant] must have provided evidence of affirmative misrepresentations of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive." *Purdue Pharma L.P. v. Boehringer Ingelheim GMBH*, 237 F.3d 1359, 1366 (Fed. Cir. 2001). When making a finding of "exceptional case" under § 285, the inequitable conduct analysis is performed in two steps: (1) the court must make a determination of whether the misrepresentation to the PTO was material and motivated by an intent to deceive, and (2) the court must weigh the level of materiality against the degree of intent in light of all the circumstances to determine whether the patentee's conduct was so culpable that the patent was issued under a cloud of deception.

The fact that the representation in the remarks portion of the amendments made to the '021 patent that the amendments contained "no new matter" was false is no longer in contention in light of the Court's ruling of March 21, 2006 (Dkt. #363). Therefore, the Court turns immediately to the materiality of that misrepresentation. There are two related standards under which a court can determine that a representation or omission during a patent prosecution was "material." The first standard, called the "reasonable examiner standard," asks whether "a reasonable examiner would have considered such [representation or omission] in deciding whether to allow the patent application." *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1363 (Fed. Cir. 2003). The second standard adopted by the Federal Circuit comes directly from the PTO's Rule 56, which

describes the duty of candor and good faith. Rule 56 reads as follows:

> [I]nformation is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
>
> (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
>
> (2) It refutes, or is inconsistent with, a position the applicant takes in:
>
> (i) Opposing an argument of unpatentability relied on by the Office, or
>
> (ii) Asserting an argument of patentability.
>
> A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

37 C.F.R. § 1.56(b) (2004). *See Purdue Pharma L.P. v. Endo Pharms. Inc.*, 438 F.3d 1123, 1129-33 (Fed. Cir. 2006) (evaluating materiality under PTO Rule 56).

Appendix F

Neutrino contends that the materiality of the "no new matter" statement is low because, at all times, the patent examiner had before him all necessary material to determine the patentability of the '021 application. Neutrino argues that the examiner was free to disagree with Redano's determination that there was no new matter and that the evidence indicates that the examiner did in fact review the specifications and the Pohl patent which served as the basis for the Court's determination that the patent was invalid. In its Reply, Sonosite argues that the statement was "clearly" material because "if Redano had told the truth, the patent would never have issued."[13] The Court is of the opinion that Sonosite has confused the materiality and intent inquiries. The question behind the materiality of Redano's statement to the PTO is not whether the PTO would have issued the '021 patent if Redano disclosed that there was new matter in the amendments, but whether the misstatement that there was not new matter could have caused the PTO to issue an invalid patent. Sonosite's formulation of the materiality inquiry assumes Redano's intent. "[M]ateriality does not presume intent, which is a separate and essential component of inequitable conduct." *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1351 (Fed. Cir. 2002) (citation omitted).

The Court finds that based on either standard of materiality adopted by the Federal Circuit, Redano's statement that there was "no new matter" in the '021 patent amendments was not material. First, the Court finds that a reasonable examiner would not have relied on Redano's statement to determine that there was not new matter in the

13. Sonosite's Reply, pp. 12-13.

amendments. As Neutrino has indicated, the patent examiner had before him all material relevant to making an independent determination of new matter as he was required to do.[14] Second, the Court finds that the statement was cumulative to other correct material already of record pertaining to the question of new matter and the statement was not inconsistent with any other position taken by Redano during the prosecution. As such, the statement that there was "no new matter" in the '021 patent application amendments was not material under either the "reasonable examiner" standard or PTO Rule 56.

Furthermore, even if the statement was material, the Court finds that Sonosite has failed to present clear and convincing evidence that Redano intended to deceive the PTO. In order for the Court to decide that this case is "exceptional" under § 285, Sonosite must present clear and convincing evidence of "actual wrongful intent . . . or of gross negligence." *Machinery Corp. of America v. Gullfiber AB,* 774 F.2d 467, 473, (Fed. Cir. 1985). The gross negligence standard has been defined as "requiring willful, wanton, or reckless misconduct, or evidence of 'utter lack of all care.'" *Id.* (quoting PROSSER AND KEETON, THE LAW OF TORTS, § 34 (4th Ed.1984)). Thus, "conduct short of fraud, but in excess of simple negligence is sufficient for deciding that the case is 'exceptional' under § 285." *Id.* (citing *Mayview Corp. v. Rodstein,* 620 F.2d 1347 (9th Cir.1980)).

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14. The statement that there is "no new matter" contained in a patent amendment is no more material than a statement by a patentee that a patent is "valid." Such representations made by a patentee would not bear upon any reasonable patent examiner's evaluation of a patent application. Such statements are legal conclusions outside of the purview of a patentee.

Appendix F

As evidence that Redano intended to deceive the PTO, Sonosite presents (1) the fact that Redano is a seasoned patent attorney who would have known the amendments contained new matter, and (2) the chronology of communications between Redano and Sonosite and other third parties indicating that Redano intended to broaden the '021 patent claims to cover certain technology being developed and marketed by Sonosite. In response, Neutrino argues that, at all times, it was Redano's intention to "completely and promptly discharge his duty of candor" to the PTO.[15] Neutrino emphasizes the fact that Redano stated his intention to disclose all pertinent art to the PTO in a letter to Dr. Solash, the thoroughness of Redano's Information Disclosure Filings, and the fact that Redano submitted the "new matter" amendment in several different filings with the PTO. Indeed, Redano testified that he "took steps to force the examiner to look at the new language twice."[16] Although there is considerable evidence that Redano intended for his portfolio of ultrasound patents to cover hand-held ultrasound technology, there is scant evidence that he intended to deceive the PTO in order to achieve this end.[17]

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15. Neutrino's Surreply, p. 11.

16. Neutrino's Response, p. 12, Deposition Testimony of Richard Redano.

17. The Court notes that the chronology of communications offered by Sonosite merely establishes that it was Redano's aim to acquire a patent that could be licensed to an existing developer of ultrasound technology. Although somewhat out-of-step with the

(Cont'd)

Sonosite further contends that Redano's deceitful intent can be discerned from the fact that he "buried" the new matter language into the amendments. However, the Court agrees with Neutrino that there is no evidence that the new matter language was buried. The order and structure of the amended claims seem perfectly rational based on the events of the prosecution and Redano's stated intention to patent hand-held ultrasound technology. Despite Redano's particular knowledge as a patent attorney, there simply is not clear and convincing evidence that Redano knew or should have known that the amended new matter was not supported by anything in the patent application. Therefore, the Court finds that Sonosite has not met its burden of producing clear and convincing evidence that Redano intended to deceive the PTO.

B. Bad Faith Litigation

In its motion, Sonosite makes allegations of both vexatious or unjustified litigation and litigation misconduct. Sonosite contends that because Redano knew that the '021 patent was invalid for new matter, he brought suit against

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(Cont'd)
original purpose of patent protection, the practice of trading in intellectual property without an intention to invest in research and development is today neither rare nor illegal. This practice, sometimes termed "patent trolling," is criticized by some as a destructive abuse of the patent system, and justified by others as increasing the liquidity of intellectual property. The Court has no reason to engage in this debate here, but notes that it limited its treatment of the "patent trolling" evidence to a possible motive to deceive as opposed to direct evidence of deceptive conduct.

Sonosite in bad faith. Sonosite further contends that Redano, in concert with Neutrino's attorneys and other third parties, improperly communicated with stock analysts and reporters about this litigation in order to coerce Sonosite into a settlement. In response, Neutrino sets forth 6 reasons why the "case was not 'clearly baseless'":

> (1) the fact that the USPTO disagrees, having examined the patent application and approved [the '021 patent];
>
> (2) the important presumption of patent validity;
>
> (3) the good faith pre-filing investigation and other efforts taken prior to filing this action;
>
> (4) this Court's previous two denials of SonoSite's Motions for Summary Judgment of invalidity;
>
> (5) this Court's Summary Judgment against SonoSite of infringement; and
>
> (6) SonoSite's own stipulation (in the submitted Joint Pre-Trial Order, willingly signed by the attorney-in-charge for both SonoSite and Neutrino) that the subject products did literally infringe the asserted patent (as construed by the Court).[18]

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18. Neutrino's Surreply, p. 15.

Neutrino also flatly denies Sonosite's allegations that it, or anyone acting on its behalf, attempted to coerce Sonosite into a settlement. Neutrino contends that all communications made with analysts or reporters were made in good faith and accurate. Sonosite does not dispute the accuracy of the information conveyed.

Based on the Court's finding above that Sonosite has failed to present clear and convincing evidence that Redano knew the '021 patent was invalid for new matter, it follows that there is insufficient evidence to establish that this litigation was unjustified or frivolous. Furthermore, the communications with stock analysts and reporters do not constitute litigation misconduct. If there was clear and convincing evidence that the litigation was brought in bad faith, then certainly evidence of Neutrino attempting to leverage a settlement would compound that bad faith. However, there is no such evidence of bad faith litigation here, where there is insufficient evidence to establish that Redano knew that the '021 patent was invalid. Therefore, the Court finds that Sonosite has failed to present clear and convincing evidence of unjustified or vexatious litigation or litigation misconduct sufficient to support a finding of exceptional case under § 285.[19]

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19. Recently, Sonosite filed additional briefing arguing Neutrino's "baseless" appeal of its case to the Federal Circuit and to the Supreme Court provides further evidence of Neutrino's vexatious litigation tactics (Dkt. #388). Neutrino filed its response (Dkt. #389). After considering the additional arguments of the parties, the Court's decision remains unchanged. The Court does not find that Neutrino's vigorous appeal of its case constituted bad faith or vexatious litigation.

Appendix F

Conclusion

The Court finds that this is not an "exceptional case" under 35 U.S.C. § 285. Therefore, Defendant's Motion for Exceptional Case and Attorneys' Fees (Dkt. # 368) is DENIED.

It is so ORDERED.

Signed this 30th day of March, 2007

s/ John D. Rainey
JOHN D. RAINEY
UNITED STATES DISTRICT JUDGE

APPENDIX G — ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF TEXAS, HOUSTON DIVISION AWARDING COSTS DATED MARCH 30, 2007

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

CIVIL ACTION NO. H-01-2484

NEUTRINO DEVELOPMENT CORPORATION,

Plaintiff,

v.

SONOSITE, INC.,

Defendant.

ORDER

Defendant Sonosite, Inc. filed an Application for Costs on April 4, 2006 (Dkt. #369). The Clerk taxed costs in the amount of $146,986.47 on April 12, 2006 (Dkt. #371). Plaintiff has filed Objections to the Bill of Costs on several grounds (Dkt. #373) and a Motion to Retax Costs (Dkt. #378). After reviewing the application, objections, and applicable law, Plaintiff's objections will be SUSTAINED in part and OVERRULED in part as explained below.

Appendix G

A. General Rules Regarding The Taxing of Costs

"Costs other than attorneys' fees shall be allowed as of course to the prevailing party unless the court otherwise directs." FED. R. CIV. P. 54(d); *accord Corpus Christi Oil & Gas Co. v. Zapata Gulf Marine Corp.*, 71 F.3d 198, 205 n.5 (5th Cir. 1995). Taxation of costs under Rule 54(d) is a matter within the court's discretion, although this discretion is limited by the express provisions of 28 U.S.C. § 1920. *See Crawford Fitting Co. v. J.T. Gibbons, Inc.*, 482 U.S. 437, 443 (1987). "The court may decline to award certain costs, but may not tax expenses that are not listed in § 1920." *Embotelladora Agral Regiomontana, S.A. de C.V. v. Sharp Capital, Inc.*, 952 F. Supp. 415, 417 (N.D. Tex. 1997); *Crawford Fitting Co.*, 482 U.S. at 441-42. Thus, a court may only tax the following as "costs": (1) fees of the clerk and marshal; (2) fees of the court reporter for all or any part of stenographic transcripts necessarily obtained for use in the case; (3) fees for printing and witnesses; (4) fees for exemplification and copies of papers necessarily obtained for use in the case; (5) docket fees; and (6) compensation of court appointed experts. 28 U.S.C. § 1920; *accord Crawford Fitting Co.*, 482 U.S. at 440; *Interstate Contracting Corp. v. City of Dallas*, 2002 U.S. Dist. LEXIS 1496, *2 (N.D. Tex. 2002). Allowable costs are limited to these categories, and expenses that are not authorized by statute must be borne by the party incurring them. *Crawford Fitting Co.*, 482 U.S. at 441-42.

If the party being taxed has not specifically objected to a cost, the presumption is that the costs being sought were necessarily incurred for use in the case and will be taxed.

See Embotelladora, 952 F. Supp. at 417 ("[I]n the absence of a specific objection, deposition costs will be taxed as having been necessarily obtained for use in the case."). However, once an objection has been raised, the party seeking costs bears the burden of verifying that the costs were necessarily incurred in the case rather than just spent in preparation and litigation of the case. *Fogleman v. ARAMCO*, 920 F.2d 278, 286 (5th Cir. 1991); *Raspanti v. U.S. Dep't of the Army*, 2001 U.S. Dist. LEXIS 14610, *38 (E.D. La. 2001). Whether a document was "necessarily obtained for use in the case is a factual determination to be made by the district court." *Fogleman*, 920 F.2d at 285–86.

B. Defendant's Bill of Costs

Defendant submitted a bill of costs in the amount of $146,986.47 for expenses it incurred in this litigation. As an initial matter, Defendant contends that Plaintiff has waived all objections because it failed to file its objections within the deadline prescribed by the Local Rules. Local Rule 54.2 requires that any objections to costs must be filed within five days of the bill being filed. S.D. TEX. LOCAL RULES 54.2. The Defendant filed its application for costs on April 4, 2006; thus, Plaintiff's objections were due April 11, 2006. *See* FED. R. CIV. P. 6(a) ("In computing any period of time prescribed or allowed by . . . the local rules of any district court . . . [and] [w]hen the period of time prescribed or allowed is less than 11 days, intermediate Saturdays, Sundays, and legal holidays shall be excluded in the computation."). Plaintiff did not file its objections until April 19, 2006.

However, although Plaintiff did not timely file its objections under the Local Rules, Plaintiff did timely file objections under the Federal Rules of Civil Procedure. Specifically, Rule 54(d)(1) permits a party to file objections within five days of the clerk's taxing costs. *See* FED. R. CIV. P. 54(d)(1) ("Such costs may be taxed by the clerk on one day's notice. On motion served within 5 days thereafter, the action of the clerk may be reviewed by the court."); *see also Marchman v. NationsBank Tex.*, 108 F.3d 333 (5th Cir. 1997) (per curiam). Thus, Plaintiff could request a review of the costs taxed and raise any objections to the bill of costs up to five days after the clerk signed it. The Clerk taxed costs on April 12, 2006, and Plaintiff filed its objections and motion to retax costs on April 19, 2006. Therefore, under the Federal Rules, Plaintiff timely filed its objections allowing this Court to review the taxation of costs. Moreover, even assuming the Plaintiff's objections are untimely, the five-day period for requesting review under the Local Rules is not jurisdictional, consequently, the Court may review the taxing of costs at its discretion. *See McLeod, Alexander, Powel & Apfel, P.C. v. Quarles*, 894 F.2d 1482, 1488 n.6 (5th Cir.1990). Utilizing its discretion in this case, the Court will consider all of Plaintiff's objections to Defendant's Bill of Costs.

The Court will now address Plaintiff's objections. First, Plaintiff argues that Defendant should be denied all costs because it comes to the Court with "unclean hands."[1] Specifically, Plaintiff contends that Defendant intentionally destroyed material evidence and engaged in abusive discovery tactics intended to drive up the costs of litigation.

1. *See* Dkt. #373, p. 1.

"Misconduct, bad faith, and abuse of the trial process are all grounds for refusing to award costs to the prevailing part[y]." *Sheets v. Yamaha Motors Corp.*, 891 F.2d 533, 539–40 (5th Cir. 1990) (taxing costs against the prevailing party for "defendants' repeated and abusive hardball tactics," including "refus[al] to produce documents in response to discovery, violating an order to compel," etc.). Neutrino attempts to reurge its previous motion for sanctions (Dkt. #334) in objecting to the Bill of Costs. During the litigation, the Court found no sanctionable conduct and denied Plaintiff's motion for sanctions as moot when it granted summary judgment in Defendant's favor. Costs are only denied in the most egregious circumstances to the prevailing party, and the Court does not find that Defendant has engaged in any inappropriate behavior justifying a denial of costs. Plaintiff has not overcome the strong presumption that the prevailing party should recover costs as a matter of course. Therefore, the Court overrules Plaintiff's objection.

Alternatively, the Plaintiff claims that the Court should reduce costs because many of Defendant's alleged costs are not recoverable and/or Defendant has not shown that the costs were necessarily incurred for use in the case. First, Plaintiff argues that the depositions for which Defendant requests costs were not necessarily obtained for use in the case. Defendant seeks $21,076.17 for transcripts of 24 depositions, including additional fees for expedited delivery, messenger delivery, E-transcripts, ASCII files on disc, and compressed transcripts. A deposition copy obtained for use during trial or for trial preparation, rather than for the mere convenience of counsel, may be included in taxable costs. *Fogleman v. Aramco*, 920 F.2d 278, 285 (5th Cir. 1991). The deposition

does not necessarily have to be used at trial, but "[i]f, at the time it was taken, a deposition could reasonably be expected to be used for trial preparation, rather than merely for discovery, it may be included in the costs of the prevailing party." *Id.*; *Stearns Airport Equip. Co. v. FMC Corp.*, 170 F.3d 518, 536 (5th Cir. 1999). All of the depositions for which Defendant seeks costs involve deponents that were listed as trial witnesses. Thus, each deposition could be expected to be used for trial purposes, as each of these witness would potentially be testifying at trial. Therefore, the Court finds the deposition costs were necessarily incurred for use at trial. Further, the Plaintiff's objections to the additional costs are overruled as moot because Defendant has voluntarily withdrawn those expenses in the amount of $2,877.50.[2]

Next, Plaintiff argues that Defendant has not shown that the copies were necessarily obtained for use in the case. Reproductions necessarily obtained for use in the case are recoverable, provided the prevailing party demonstrates that necessity. *Fogleman*, 920 F.2d at 286. Itemized breakdowns assist the court in distinguishing the copies obtained for use in the case and those obtained simply for the convenience of counsel. *Id.* While the court does not expect a prevailing party to identify every xerox copy made for use in the course of legal proceedings, it does require some demonstration that reproduction costs necessarily result from that litigation. *Id.*; *See Summit Tech., Inc. v. Nidek Co., Ltd.*, 435 F.3d 1371, 1378 (Fed. Cir. 2006) ("We agree with [defendant] that, in complex patent litigation involving hundreds of thousands of documents and copies, parties cannot be expected to track the identity of each photocopied page along with a record of its relevance to the litigation.").

2. *See* Dkt. #376, pp. 7–8.

Here, the Defendant seeks $115,205.21 for exemplification and copying expenses. Defendant has provided an itemization of copying expenses, along with invoices for copies produced from outside vendors for patents, non-patent prior art, and documents produced, among other things. Plaintiff argues that numerous copies were made for the convenience of counsel, including "decisions from official reporters, articles, research and text from treatises."[3] Defendant avers that large amounts of photocopying was required because of the scope and complexity of this patent dispute. The Court agrees that the complexity of patent litigation requires extensive document production and it is often necessary for complete trial preparation. Therefore, the Court finds that the costs incurred by Defendant for copies in the various categories listed above were necessary for use in this case that Plaintiff initiated against Defendant.

Plaintiff also contends that Defendant cannot recover for the production costs of exhibits absent pretrial approval from the court. The Fifth Circuit has held that "absent pretrial approval of the exhibits . . . a party may not later request taxation of the production costs to its opponent." *La. Power & Light Co. v. Kellstrom*, 50 F.3d 319, 335 (5th Cir. 1995). However, in *Kellstrom*, the Fifth Circuit was referring to physical, demonstrative trial exhibits. *Id.; see also Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 1995 WL 813691, *5 (N.D. Tex. 1995) ("The law in this Circuit permits taxation of costs for demonstrative evidence only if there is pretrial authorization by the trial court."). Defendant does not seek to recover costs incurred in producing physical trial exhibits, but only for copies of exhibits needed for use in depositions.

3. *See* Dkt. #373, p. 5.

This cost is recoverable under § 1920(2) as a cost included in reproducing depositions that are necessarily obtained for use in the case. *See Anderson v. Siemens Med. Sys., Inc.*, 2002 WL 199878, *5 (N.D. Tex. 2002) (finding the costs for "deposition transcripts and exhibits" were recoverable); *Lovell v. Glen Oaks Hosp., Inc.*, 1999 WL 1029091, *3 (N.D. Tex. 1999) (holding that exhibits attached to plaintiff's deposition were taxable). Therefore, the Court will overrule Plaintiff's objection because the expenses incurred involved only exhibits used in association with depositions, which the Court has previously found were necessary for use in this case.

Next, the Plaintiff argues the $541.25 cost for "removing metadata from files to be produced electronically" is not recoverable because it is not an enumerated expense under § 1920. As explained above, reproduction costs necessarily obtained for use in the case are recoverable, provided the prevailing party demonstrates that necessity. *Fogleman*, 920 F.2d at 286. In this instance, the electronic data was produced in lieu of costly paper production. Defendant was seeking to save costs by not printing out hundreds of documents, which required redaction of privileged information. This electronic production in response to Plaintiff's discovery request falls within costs recoverable for "fees and disbursements for printing." 28 U.S.C. § 1920(3), and therefore the Court will overrule Plaintiff's objection.

Finally, the Court is required to give "careful scrutiny" to the costs submitted by the prevailing party. *Farmer v. Arabian Am. Oil Co.*, 379 U.S. 227, 235 (1964). After carefully scrutinizing the Defendant's application for costs,

the Court did discover a duplicate entry of $387.42 in Defendant's requested copying costs.[4] Also, after reviewing the invoices related to the deposition costs, the Court also found that Defendant was charging the late payment fee of $1,997.25 instead of $1,877.41, amounting to a difference of $119.84.[5] The Court will not charge Plaintiff for the increased cost relating to those bills paid after 30 days, according to the invoice. Therefore, the Court will deduct these extraneous expense from the Defendant's Bill of Costs by $507.26.

Conclusion

Defendant requested taxable costs in the amount of $146,986.47. Defendant voluntarily withdrew costs in the amount of $2,877.50, and the Court reduced costs by $507.26. Accordingly, it is ORDERED that Defendant shall recover from Plaintiff $143,601.71 for the costs incurred in litigating this dispute.

It is so ORDERED.

Signed this 30th day of March, 2007.

s/ John D. Rainey
JOHN D. RAINEY
UNITED STATES DISTRICT JUDGE

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4. *See* Dkt. #369, ex. E.2, entry 64 & 65.

5. *See* Dkt. #369, ex. B, entry 5.

APPENDIX H — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DENYING PETITION FOR REHEARING DATED AND FILED JANUARY 19, 2007

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2006-1316

NEUTRINO DEVELOPMENT CORPORATION,

Plaintiff/Counterclaim Defendant-Appellant,

and

RICHARD T. REDANO,

Counterclaim Defendant,

v.

SONOSITE, INC.,

Defendant/Counterclaimant-Appellee.

ORDER

A combined petition for panel rehearing and for rehearing en banc having been filed by the Appellant, and the petition for rehearing, having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc having been referred to the circuit judges who are in regular active service,

Appendix H

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on January 26, 2007.

FOR THE COURT,

s/ Jan Horbaly
Jan Horbaly
Clerk

Dated: 01/19/2007

APPENDIX I — ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF TEXAS, HOUSTON DIVISION DATED AUGUST 20, 2003

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

CIVIL ACTION NO. H-01-2484

NEUTRINO DEVELOPMENT CORPORATION,

Plaintiff,

v.

SONOSITE, INC.,

Defendant.

ORDER

This is an action for patent infringement brought by Neutrino Development Corporation ("Neutrino") against SonoSite, Inc. ("SonoSite"). Neutrino is the owner of United States Patent No. 6,221,021 ("the '021 Patent"). Neutrino alleges that four devices manufactured and marketed by SonoSite, Inc. ("SonoSite"), the SonoSite 180, SonoHeart, SonoSite 180 PLUS, and SonoHeart PLUS, infringe on the '021 Patent. On February 20, 2002 the Court held a *Markman* hearing to construe the claims of the '021 Patent.

Appendix I

THE PATENTED DEVICE

The '021 Patent is titled "Method and Apparatus for Penile Hemodynamic Stimulation, Monitoring, and Drug Delivery Acceleration" and describes a device for "stimulating and/or monitoring hemodynamic activity, such as blood flow, in a penis." *US. Patent No. 6,221,021* at col. 1, ll. 15-16. This device operates by "coupling . . . an ultrasound source to the outer surface of the penis and transmitting ultrasound energy into the penis at a sufficient frequency and intensity to increase hemodynamic activity." *Id.* at col. 1, ll. 18-21. The device fits around the penis when in use and is operated using a pistol-type grip.

DISPUTED CLAIMS

There are 27 claims in the '021 Patent. Of these claims, three, 8, 20, and 25, are independent. It is these three independent claims that form the primary nexus of dispute in this case. Each of the three independent claims contain very similar language. Claim 20 is representative:

> A hand held apparatus capable of displaying measured hemodynamic parameters, comprising:
>
> a. a portable body sized to be hand held;
>
> b. an ultrasonography generator mounted in said body and capable of measuring one or more hemodynamic parameters, said generator comprising a display capable of displaying at least one measured hemodynamic parameter;

> c. a transducer mounting assembly moveably connected to said body such that the distance between said assembly and said body can be adjusted by a user using only one hand;
>
> d. at least one ultrasound emitter mounted in said assembly; and
>
> e. a triggering mechanism connected to said generator and capable of actuating said generator

Id. at col. 9, l. 29 to col. 10, l. 4. The following claim terms are in dispute: 1) "a transducer mounting assembly moveably connected to said body such that the distance between said assembly and said body can be adjusted by a user using only one hand;" 2) "a portable body sized to be hand held;" and 3) "ultrasound emitters."[1]

CLAIM CONSTRUCTION STANDARD

In construing the claims of a patent the court must consider all of the intrinsic evidence, that is, the claims, the specification, and the prosecution history. *Vitrionics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Patents are technical documents which are meant to instruct

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1. The parties have also engaged in some debate as to the meaning of the following terms: 1) "mounted in," "mounted on," "housed within," and "top surface;" 2) "portable body comprising a top surface;" 3) "connected to" and "coupled to;" 4) "generating an instruction;" and 5) "display." These terms are unambiguous and do not need to be interpreted by the Court.

and inform those skilled in the art and "the court must determine how a person of experience in the field of [the] invention would, upon reading the patent documents, understand the words used to define the invention." *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1299 (Fed. Cir. 1999). Thus, claim terms are not construed in a "lexicographic vacuum, but in the context of the specifications and drawings," *id.* at 1301, and "dictionary definitions of common words are often less useful than the patent documents themselves in establishing the usage of ordinary words in connection with the claimed subject matter." *Id.* at 1299; *see also Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.2d 1473, 1478 (Fed. Cir. 1998) ("Courts must exercise caution lest dictionary definitions, usually the least controversial source of extrinsic evidence, be converted into technical terms of art having legal, not linguistic, significance."). In addition, a claim construction that does not cover a preferred embodiment disclosed in the specification is "rarely, if ever, correct." *Vitrionics*, 90 F.3d at 1583.

There is a certain tension, however, between the rule requiring courts to interpret claim terms in light of the patent specification and another basic axiom of patent law, that is, that claim terms should not be limited to the preferred embodiment. *N. Telecom Ltd. v. Samsung Elecs. Co.*, 215 F.3d 1281, 1293 (Fed. Cir. 2000). The Federal Circuit has offered the following clarification:

> Although it is entirely proper to use the specification to interpret what the patentee meant by a word or phrase in the claim, . . . this is not to

> be confused with adding an extraneous limitation appearing in the specification, which is improper. By "extraneous," we mean a limitation read into a claim from the specification wholly apart from any need to interpret . . . particular words or phrases in the claim.[2]

In re Paulson, 30 F.3d 1475, 1480 (Fed. Cir. 1994) (quoting *E.I. Du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 1988)).

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2. The difficulty with this explanation is that the process of interpretation is, by its nature, also a process of limitation. Claim construction is the mechanism by which the precise meaning of a patent's claims becomes legally fixed. Adopting any particular claim construction necessarily entails rejecting other possible claim constructions, thereby reducing the universe of possible meanings attributable to a given claim. Therefore, because the specification must be used to construe claims, the specification will always play a role in limiting the patent's claims. Thus, courts must attempt to determine whether a particular claim construction would improperly impose an "extraneous" limitation from the specification on the claims or simply explicate and clarify the claim terms in light of the description of the invention contained in the specification. In regards to this process the Federal Circuit has noted that: "Although precedent offers assorted quotations in support of differing conclusions concerning the scope of the specification, these cases must be viewed in the factual context in which they arose." *Wang Labs., Inc. v. Am. Online, Inc.*, 197 F.3d 1377, 1383 (Fed, Cir. 1999). Thus, it is "as clear as is the summer's sun." WILLIAM SHAKESPEARE, THE LIFE OF KING HENRY THE FIFTH act. 1, sc. 2.

Appendix I

ANALYSIS

I. The Moveably Connected Transducer Mounting Assembly

Neutrino has advanced the following proposed construction of the "moveably connected transducer mounting assembly" limitation:

> An assembly sized to contain at least one ultrasound emitter or transducer, which is connected to the portable body such that a user of the apparatus can cause a change in the distance between the transducer mounting assembly and the portable body, using only one hand.

SonoSite has offered the following construction:

> A structure that maintains the transducer mounting assembly a distance from the portable body to envelope an organ,[3] having a mechanism that permits the user to adjust the distance using only one hand.

The Court believes that Neutrino's proposed claim construction is a more accurate interpretation of the '021 Patent.

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3. Initially SonoSite argued that the transducer mounting assembly was limited to a structure designed to envelope a penis. At the *Markman* hearing, SonoSite acknowledged that the '021 Patent is not so limited and that a structure specifically designed to envelope a penis is not required by the claims.

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The preferred embodiment of the '021 Patent device is depicted in Figure 2 of the patent which is reproduced below.

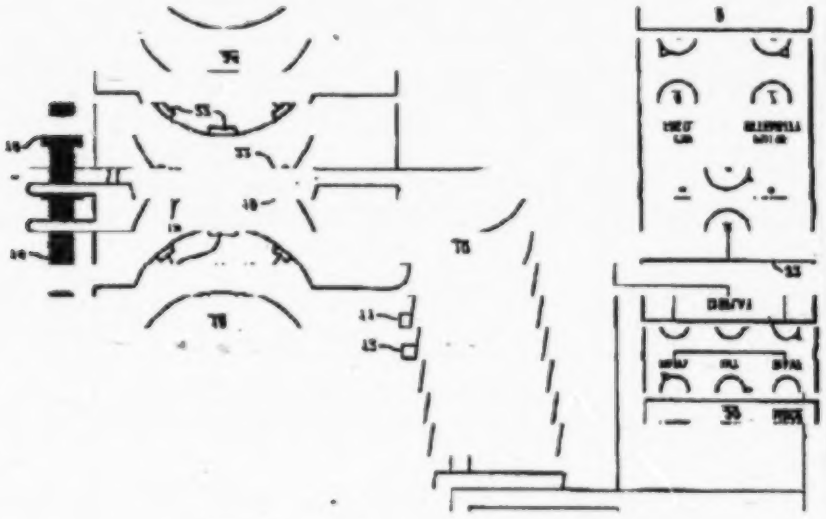

FIG. 2

In this diagram the component labeled "9" is "an ultrasound generator . . . sized to be grasped or held in a user's hand." *US. Patent No. 6,221,021* at col. 4, ll. 33-39. Component 30 is "the ultrasonography generator" which is also "sized to be grasped or held in a user's hand." *Id.* at col. 6, ll. 18-20. Component 10 is a "portable housing coupled to the ultrasound generator." *Id.* at col. 4, ll. 33-34. Components 18 and 24 are, respectively, the upper and lower transducer mounting assemblies. *Id* at col. 4, ll. 42-44; col. 5, ll. 26-28. Components 14 and 16 are a threaded rod and adjusting wheel which make up the axial position adjuster. The '021 Patent's specification describes a device containing two transducer

mounting assemblies, an upper mounting assembly and a lower mounting assembly:

> . . . The housing comprises at least one ultrasound trigger and a first transducer mounting assembly. The invention further comprises a position adjuster coupled to the first transducer mounting assembly and a second transducer mounting assembly mounted across from the first transducer mounting assembly. The second transducer mounting assembly is coupled to the position adjuster.
>
> A first ultrasound emitter is mounted in the curved lower transducer mounting assembly. The first ultrasound emitter is connected to the ultrasound trigger and to the ultrasound generator. A second ultrasound emitter is mounted in the curved second transducer mounting assembly. The second ultrasound emitter is connected to the ultrasound trigger and to the ultrasound generator. . . .

Id. at col. 3, l. 67 to col. 4, l. 13. The description of the preferred embodiment is similar:

> The invention further comprises a second transducer mounting assembly 24 mounted across from the first transducer mounting assembly. As shown in FIG. 2, the position adjuster permits the distance between the housing 10 and mounting assembly 24 to be adjusted by the user using one

> hand. In the preferred embodiment shown in FIG. 2, the mounting assembly 24 is moveably connected to the housing 10. In a preferred embodiment, the second transducer mounting assembly is mounted in alignment with the first transducer mounting assembly. In another preferred embodiment, the second transducer mounting assembly is curved. The second transducer mounting assembly is coupled to the position adjuster. The radii of curvature of the first and second transducer mounting assemblies are sized such that the first and second transducers can be coupled to the outer surface of a penis.

Id. at col. 5, ll. 26-41.

It appears that the device described in the '021 Patent contains two transducer mounting assemblies that together perform the penis enveloping function described in the specification. The axial position adjuster holds the upper and lower transducer mounting assemblies in a fixed position relative to each other so that the device can perform this penis enveloping function. However, the axial position adjuster does not connect either the ultrasound or the ultrasonography generator to either transducer mounting assembly. In addition, while the housing (number 10 in Figure 2) is described as being portable and, because it has a pistol-type grip, *id.* at col. 5, l. 16, it is presumably intended to be hand held, it is not reasonable to read the specification as placing either the ultrasound or the ultrasonography generator within this housing as SonoSite suggests doing. There is no indication of such a configuration in either the specification or the

drawings. In addition, the ultrasound generator has control knobs mounted on it and the ultrasonography generator has both control knobs and a display. Thus, it is very counterintuitive to place these components inside the housing or to somehow merge them with the portable housing. The specification and the claims both indicate that although the housing, the ultrasound generator, and the ultrasonography generator are all designed to be portable and hand held, each is a separate and distinct component of the patented device. Thus, the specification does not support SonoSite's contention that the transducer mounting assemblies must be maintained at a fixed distance from either the ultrasound or the ultrasonography generator.

In support of its proposed claim construction SonoSite also relies on the patent examiner's initial rejection of claim 20 for obviousness-type double patenting. The preexisting patent with which claim 20 of the '021 Patent came into conflict was United States Patent No. 5,931,783 ("the '783 Patent"), which is also owned by Neutrino. The '783 Patent describes a portable ultrasound device very similar to the '021 Patent but which includes a limitation requiring the connection between the ultrasound generator and the transducer mounting assemblies to consist of a screw-like apparatus identical to the axial position adjuster described in the '021 Patent specification. In fact, the diagram identified as "Figure 2" in the '021 Patent is also included in the '783 Patent. The patent examiner stated that,

> [a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because the axial positioning adjuster as claimed

> in the portable ultrasound generating apparatus therein described is effectively a narrower recitation of a one-handedly adjustable moveable tranducer mounting assembly as called for in the current base claims.

Communication from U.S. Patent Office to Richard T. Redano dated October 25, 2000 at ¶ 2. This implies that the patent examiner understood the moveable connection in the '021 Patent to be the axial position adjuster and not the connection between the ultrasound and the ultrasonography generator and the housing on which the transducer mounting assemblies are located, as urged by Neutrino.

SonoSite argues that the double patenting rejection "suggests that the Examiner was viewing the amended claims from the perspective of obvious variations of the original penis-enveloping structure . . . and not as a fundamentally different and non-obvious structure." *Def.'s Mot. for Summ. J.* at 20. While this may be true, it does not mean that the patent examiner believed that the moveable connection described in the '021 Patent would be the threaded rod connector described in the '783 Patent. The '783 Patent is merely a species of the genus '021 Patent. *See In re Goodman*, 11 F.3d 1046, 1052-53 (Fed. Cir. 1993). Because "the generic invention is 'anticipated' by the species of the patented invention. . . . without a terminal disclaimer, the species claims preclude issuance of the generic application." *Id.* at 1053. But, it would be a mistake to assume that the specific claims in the species patent are necessarily limitations on the generic claims in the genus patent. It appears that the patent examiner simply viewed the threaded rod connector

as a type of moveable connector and not an identical structure. This conclusion is supported by *In re Goodman* and similar cases which have consistently viewed the double patenting inquiry as consisting of two parts: 1) a determination of whether or not the competing patents are identical in scope, resulting in a rejection of the subsequent patent under 35 U.S.C, § 101, and 2) a determination of whether the subsequent patent is merely an obvious variation of the first, resulting in rejection under the judicially created doctrine of obviousness-type double patenting. *Id.* at 1052; *see also Gerber Garment Tech., Inc. v. Lectra Sys., Inc.*, 916 F.2d 683, 686 (Fed. Cir. 1990); *In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985). Because the patent examiner's initial rejection of the '021 Patent was based on the judicial doctrine and not § 101, this implies that the patent examiner viewed the '783 Patent as nothing more than a more narrow version of the '021 Patent and not as an identical apparatus.

The Court adopts Neutrino's construction of the "moveably connected transducer mounting assembly" limitation.

II. A Portable Body Sized to be Hand Held

Neutrino has advanced the following proposed construction for the "portable body sized to be hand held" limitation:

> A body that is small and light enough to be held in one hand for the duration of an ultrasound examination to measure a hemodynamic parameter in a patient.

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SonoSite has offered the following construction:

> A body that is sized such that it can be held by hand and, so held, moved from one location to another.

Although Neutrino's proposed construction is more consistent with the common understanding of the term "hand held" as that term is used to describe electronic devices such as computers, Neutrino's proposed interpretation is foreclosed by the patent specification.

Properly adjusting the distance between the two transducer mounting assemblies described in the preferred embodiment is very important:

> It is known in the ultrasound arts that a satisfactory ultrasound coupling is necessary for effective delivery of ultrasound energy to a patient for therapeutic or diagnostic purposes. The position adjuster provides a mechanism for maintaining a satisfactory ultrasound coupling as the penis expands circumferentially as a result of increased hemodynamic activity.

US. Patent No. 6,221,021 at col. 5, ll. 1-5. The specification also states that, "[t]he placement of the triggers and axial position adjuster on opposite sides of the housing facilitates the user's ability to easily use both hands to simultaneously manipulate the trigger and the position adjuster." *Id.* at col. 5, ll. 22-25. Thus, if the Court adopted Neutrino's proposed claim construction, in order to operate the device

described in the preferred embodiment, the user would need one hand to hold the ultrasound generator, one hand to hold the pistol grip (where the buttons that turn the device on are located), and one hand to adjust the axial position adjuster. Obviously this is an impossible arrangement for one person. However, the specification also states that, "[t]he apparatus and method of the present invention may be practiced by the patient, after proper training, without assistance from another person." *Id.* at col. 5, ll. 13-15. Thus, a third-party cannot relieve Neutrino of this difficulty. Because Neutrino's proposed construction would exclude the preferred embodiment from the patented claims, it must be rejected.

The Court adopts SonoSite's construction of the "portable body sized to be hand held" limitation.

III. Ultrasound Emitters

Neutrino has advanced the following proposed construction of the "ultrasound emitter" limitation:

> At least one component, also known as a "transducer" or "emitter," and capable of emitting ultrasound energy.

SonoSite has offered the following construction:

> Mechanisms that are solely capable of emitting ultrasound waves, a one-way function, rather than emitting and receiving ultrasound waves, a two way function.

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Although SonoSite's proposed construction is more consistent with the normal understanding of the term "emitter" as that term is used in the ultrasound arts, it is inconsistent with the manner in which the word "emitter" is used in the '021 Patent and therefore, must be rejected.

As even SonoSite acknowledges, *Def.'s* Markman *Br. Regarding Construction of the Claims of [the '021 Patent]* at 56, the '021 Patent's specification uses the terms "emitters" and "transducers" interchangeably:

> A first ultrasound *emitter* 19 is mounted in the first transducer mounting assembly. The first *transducer* is connected to the ultrasound trigger and to the ultrasound generator. . . .
>
> A second ultrasound *transducer* 22 is mounted in the second transducer mounting assembly, as shown in FIG. 2. The second ultrasound *emitter* is connected to the ultrasound trigger and to the ultrasound generator. . . .

U.S. Patent No. 6,221,021 at col. 5, ll. 42-54 (emphasis added). While it is presumed that claims have the meaning which would normally be attributed to them by someone skilled in the relevant art, this presumption can be overcome when the patentee has chosen to be his own lexicographer. *Tate Access Floors, Inc. v. Interface Architectural Res., Inc.*, 279 F.3d 1357, 1370 (Fed. Cir. 2002). If a patentee wishes to use a term in a manner inconsistent with its commonly understood meaning in the art, he must do so clearly. *Id.* However, a claim term may be given a novel meaning by

implication and the primary inquiry is always whether the intrinsic evidence would put someone skilled in the art on notice that the patentee was redefining an otherwise clear term. *Bell Atl. Network Serv's., Inc. v. Covad Communications Group, Inc.* , 262 F.3d 1258, 1268 (Fed. Cir. 2001). The '021 Patent's specification clearly uses the terms "emitter" and "transducer" interchangeably and thus the claim construction advanced by SonoSite is contrary to the intrinsic evidence.[4]

The Court adopts Neutrino's construction of the "ultrasound emitter" limitation.

CONCLUSION

The Court construes the following claim terms from the '021 Patent as follows:

(a) "A transducer mounting assembly moveably connected to said body such that the distance between said assembly and said body can be adjusted by a user using only one hand"— An assembly sized to contain at least one ultrasound emitter or transducer, which is connected to the portable body such that a user of the apparatus can cause a change in the distance between the transducer mounting assembly and the portable body, using only one hand.

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4. Of course, using terms with distinct meanings in the art interchangeably may result in serious invalidity problems. Such muddled nomenclature may deprive the patent of the clarity required by 35 U.S.C. § 112 or draw prior art within the scope of the patent.

(b) "A portable body sized to be hand held"—A body that is sized such that it can be held by hand and, so held, moved from one location to another.

(c) "Ultrasound emitter"—At least one component, also known as a "transducer" or "emitter," and capable of emitting ultrasound energy.

(b) It is so ORDERED

Signed this 20th day of August, 2003.

s/ John D. Rainey
JOHN D. RAINEY
UNITED STATES DISTRICT JUDGE

APPENDIX J — RELEVANT STATUTES

35 U.S.C.A. § 112

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A claim may be written in independent or, if the nature of the case admits, in dependent or multiple dependent form.

Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

A claim in multiple dependent form shall contain a reference, in the alternative only, to more than one claim previously set forth and then specify a further limitation of the subject matter claimed. A multiple

dependent claim shall not serve as a basis for any other multiple dependent claim. A multiple dependent claim shall be construed to incorporate by reference all the limitations of the particular claim in relation to which it is being considered.

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

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35 U.S.C.A. § 132

(a) Whenever, on examination, any claim for a patent is rejected, or any objection or requirement made, the Director shall notify the applicant thereof, stating the reasons for such rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application; and if after receiving such notice, the applicant persists in his claim for a patent, with or without amendment, the application shall be reexamined. No amendment shall introduce new matter into the disclosure of the invention.

(b) The Director shall prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant. The Director may establish appropriate fees for such continued examination and shall provide a 50 percent reduction in such fees for small entities that qualify for reduced fees under section 41(h)(1) of this title.